

**PHARMACEUTICAL CARE
IN THE
CALIFORNIA WORKERS' COMPENSATION
INSURANCE SYSTEM**

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**REPORT:
PHARMACY AND COMMERCIAL INSURANCE
SURVEY RESPONSES**

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OBJECTIVE: The objective of the study is to determine the response of pharmacies and insurers to the legislated Workers' Compensation policies SB228 and AB227, to change the current workers' compensation pharmacy fee schedule to 100% Medi-Cal pharmacy payments including mandatory generic substitution to anyone dispensing drugs. The current fee schedule until 1/1/2004 is:

For Brand name drugs: $1.1 \times \text{AWP} \times \text{Quantity} + \4.00 dispensing fee
For Generic drugs: $1.4 \times \text{AWP} \times \text{Quantity} + \7.50 dispensing fee

The new law requires the use of 100% of the Medi-Cal pharmacy schedule which pays the lower of:
(AWP-10% + \$3.55) – 5%, or (MAC + \$3.55) – 5% or (Usual and Customary fee) – 5%.

We asked in our survey for the opinions of pharmacists and insurers about current reimbursement practice (the period prior to the enactment of the 100% Medi-Cal pharmacy schedule), responses to the new bill requiring the use of the Medi-Cal system for drug payment, and access issues.

METHODS: We conducted a convenience survey of pharmacies and workers' compensation insurers in the state of California from July, 2003 to January, 2004.

We surveyed two types of pharmacies:

1. Large and mid-size chain pharmacies and
2. Independent pharmacies

We surveyed two main types of insurers:

1. Commercial insurers and
2. Self-insured providers: Many of the self-insured providers obtained help from their billing departments or their TPAs or PBMs in providing answers to the survey as they were unfamiliar with the workers' compensation business. Their responses were therefore much more complex to obtain and our lower response rate for this group reflects this.

Population/Sampling:

Pharmacies: We obtained our sampling frame for the independent pharmacies from a list of pharmacy site licenses from the California Board of Pharmacy listed on their web

site (www.pharmacy.ca.gov) on August 29, 2003. They provided a list of 2,208 independent pharmacies by their name, license code number and location. We randomly selected 300 independent pharmacies and called them to ask for their participation and ask that they provide a fax number or email for delivery of the survey to them. Many pharmacies (20%) were eliminated because they no longer were doing business, or provided a specialty service which did not include the workers' compensation population. This led to a total population of 1766 pharmacies in California who were eligible to participate, and 240 independent pharmacies that we called and asked to participate. We received 108 responses which represent 6.1% of the total independent pharmacy population.

The population of chain pharmacies was obtained from this same list of pharmacy site licenses. The chain pharmacies had anywhere from 10 to 550 stores and were identified on our list because they had an extra "headquarters" license on our list, or when called, they identified themselves as a chain drug store. We excluded HMO pharmacies. There were 17 of these chain pharmacies which included both supermarket chains and large drug store pharmacies. 12 chain pharmacies responded in part or whole for a response rate of 70.5% by 12/19/2003. These chains represented a total of 2,724 individual pharmacy stores in California. We surveyed a senior manager of pharmaceutical operations for California after we obtained permission from them over the telephone to email them our web-based survey. Most of these individuals completed the survey on-line but they had an option to complete a mailed or faxed version as well. Several of these chain pharmacies indicated that they had a policy never to fill out any surveys and declined on that basis.

Insurers: We obtained our population of workers' compensation insurers from a 2002 list of workers' compensation companies from the California Department of Insurance (Web site: www.insurance.ca.gov.) which listed the companies by market share. After calling and eliminating those that had stopped doing business in California, or merged with others, we selected a population that represented about 80% of our listed market share which resulted in a sample of 37 commercial insurers that when questioned actually now represented 99% of their reported market share. We surveyed the manager of workers' compensation that included the California business for each insurer. We called them and obtained their permission to email, fax or mail a survey to them for completion. Most of these individuals filled out the survey on-line. We had a population of 37 commercial insurers and 23 responded, as of 3/01/2004, for a response rate of 62% for commercial insurers which represented 99% of the total market share of workers' compensation business in California.

Our population of self-insured employers was obtained from the Department of Industrial Relations web site list (Feb. 22, 2003), (www.dir.ca.gov). From a total number of 325 private self-insured providers and 384 public self-insured providers listed, we randomly selected a sample of 229 subjects (120 public and 109 private self-insured workers' compensation providers) who were emailed a survey after obtaining consent from the manager of workers' compensation. It was more difficult to obtain surveys from this

group because the self-insured manager often did not know enough about their workers' compensation business to answer all of the questions and needed to forward the survey to their outsource company for them to fill out. However, our self-insured manager remained our primary contact. The TPA out sourced was made aware they were filling out the survey from the perspective of only that self-insured company. In some cases the self-insured workers' compensation manager and TPA manager completed the survey together. As of 03/01/2004 we had a response rate of 28.4% of self-insured providers (30% public and 27% private self-insured providers). This represents about 9% of the total self-insured provider population.

Surveys: We created 2 separate surveys for pharmacies, one for independent pharmacies, and one for chain pharmacies, which differed only in the questions that related to having more than one store. We also had separate surveys for the commercial and the self-insured insurers. All surveys addressed the following major concepts:

1. Demographics
2. Current practices with current fee schedule
3. Reactions to the proposed change to 100% Medi-Cal
4. Price sensitivity to changes
5. Ability to provide discounts
6. Incentives and disincentives used
7. Patient Access issues
8. Ability to negotiate contracts
9. Administrative difficulties in relationships with others
10. Top 5 drugs by volume for workers' compensation clients

The surveys were from 33 to 37 questions long and required likert scales, listing, fill in the blank, and ranking type responses. The surveys were available on-line through a web-based system from email, but also were mailed or faxed if requested. There was also room given for open-ended responses. Participants were allowed to omit any items that they didn't know the answer to or did not wish to answer. The survey took from 15 to 40 minutes to complete.

Analysis: Analysis consists of frequencies of responses. The commercial insurers were analyzed by market share and by individual response to provide more weight to those who affect more of the market, yet to provide a fair view about the effects the policy may have on each individual business. When viewing the market share analysis, it is important to realize that there were omitted responses on many selected questions, by various responders. We report frequencies of those that responded so it precludes one from knowing from these results how those with larger market shares really responded to any individual question because they many not have responded to any particular question. We also combined responses to give less indication of which individual response was given by companies with larger market shares and thus allow them to retain their anonymity.

RESULTS:

Pharmacies:

Demographics:

Chain Pharmacies: The chain pharmacies were proportionally distributed across all of California. They had 10 to 500 pharmacies in California, and from 15 to 1600 California FTE pharmacists, filling from 1,000 to 2,700,000 prescriptions per month. All respondents reported that from 60-100% their pharmacies filled at least 1 workers' compensation claim in the last year and 44% reported that 8-15% of their profits were from workers' compensation claims, with another 22% indicating 4-8% profits, and another 22% 1-3% of their profits from workers' compensation. 11% of respondents indicated that workers' compensation represented > 25% of their overall profits.

Independent Pharmacies: The independent pharmacies were also proportionally distributed across all areas of California. They ranged from 1 to 7.5 FTE pharmacists and filled from 165 to 11,000 prescriptions per month total. The majority (81%) of independent pharmacies reported that workers' compensation claims represented <=5% of all their prescriptions, with 17% reporting more than 5% of prescriptions filled for workers' compensation claimants. The majority (42%) of independent pharmacies reported that workers' compensation pharmacy claims represented from 1-3% of their overall profit, although 19% reported that WC represented from 8-15% of their profit and 9.4% reported WC was 16-25% of their overall profit.

Current Practices (before 1/2004):

The majority (58.3%) of chain pharmacies currently bill insurers equal to the Official Medical Fee Schedule (OMFS), with 25% billing somewhat more than the OMFS. Yet the majority (50%) report that they get paid somewhat less than the OMFS, although 33% reported getting paid equal to the OMFS and 8% reported getting paid much less.

Independent pharmacies indicate that they bill either equal to (38%) or somewhat more than (31%) than the OMFS, yet the majority of independents also report they are paid somewhat less than (41%) or equal to (32%) the OMFS. 17% of independent pharmacies report getting paid much less, and 9% paid somewhat more than the OMFS.

57% of chain pharmacy respondents reported that the current pharmacy fee schedule for workers' compensation patients in California "fairly compensated them for their services, although 29% reported being slightly and (15%) completely under-compensated on the current system.

The majority (47%) of the independent pharmacies report (similarly to the chain pharmacies) that the current pre-Medi-Cal fee schedule system fairly compensates them, with 26% reporting they are slightly under-compensated, and another 24% feel completely under-compensated; more than the chain pharmacies. Only 3% of

independent pharmacies report being currently somewhat generously compensated while none of the chain pharmacies reported this.

Effects of change to 100% Medi-Cal pharmacy system:

69% of chain pharmacy respondents reported that when moving to 100% Medi-Cal fee schedule the AWP discount change will have a strong negative affect on their business, with an additional 23% reporting the change will have a slight negative effect on them. The change in dispensing fee is not quite as problematic, with 58% reporting a strong negative effect, 17% a slight negative effect and 17% neutral to the change in dispensing fee. The change to mandatory generics was much less bothersome to the chain pharmacies with 74% reporting a slight positive effect or neutral effect, and 27% reporting a slight or strong negative effect with the change to mandatory generics.

The independent pharmacies reported a larger negative affect than did the chain pharmacies, from the change to 100% Medi-Cal pharmacy system with 76% reporting a strong negative and 14% a slight negative effect on them from the AWP change and 65% and 24% reporting a strong and slight negative effect on them from the dispensing fee change. Again the change to AWP is expected to affect them more negatively than the change to dispensing fee. The majority of both types of pharmacies think that the generic mandate will have a neutral affect on them, probably because they are already engaging in significant generic substitution, although 34% of the independent pharmacist think generic substitution will have either a slight or strong negative effect on them

Business viability was reported by chain pharmacies to be affected negatively with the anticipated change to 100% Medi-Cal, but this effect was reported to be variable depending on the type of pharmacy. (see table 1). Taking both the fee schedule change and the generic mandate into account, the majority of chain and independent pharmacies report that their annual profits will be reduced. 58% of chain pharmacy respondents reported that their profits would be reduced by 16-30%, and 25% reported anticipated profit reductions between 31 and 50%. 34% of independent pharmacies reported that their profits would be reduced by 16-30%, 28% reported expected profit reductions of 6-15% and 22% reported profit reductions of as much as 31-50%. This demonstrates that the change to the Medi-Cal fee schedule is expected to have a greater

Table 1:

Business Viability with 100% Medi-Cal: How easy to stay in business?						
12/19/2003 data			%	%	%	%
	Large Chain pharmacies:		very hard	hard	little/no effect	Improve
	Lrg Chains		8	33	68	
	Independent		50	42	8	
	Sm Chains		25	67	8.3	
	Mass Mrkt			33	67	
	Super Mrkt			33	67	
	Mail Order			9	50	42
	Independent Pharmacies					
	Lrg Chains		4	21	67	7
	Independent		36	50	13	1
	Sm Chains		19	52	29	
	Mass Mrkt		3.9	16	67	12
	Super Mrkt		7	15	68	9
	Mail Order		7	16	55	22

Table 1 shows the variable responses of each group but all generally responded that the change to 100% Medi-Cal reimbursement would have the largest negative effect on the small independent pharmacies, middle effects on small chain pharmacies, and a negative but less negative effect on the large chains. For example, 92% of the chain pharmacies and 86% of the independent pharmacies reported that it would be hard or very hard for independent pharmacies to stay in business. But only 41% of chains and 25% of independents thought it would be hard or very hard for large chains to stay in business with the new Medi-Cal payment system requirements. Most felt that the 'mail order' pharmacies would be the only ones to be positively affected by the pharmacy fee schedule proposed change.

Ability to shift losses to others: The chain pharmacies mostly (55% to 82%) reported that they would be unable to shift their losses to other entities. Generally the chain pharmacies reported the ability to shift the most losses to other non-workers' compensation clients, PBMs/TPAs, and insurance companies. The independent pharmacies felt much less able than the chain pharmacies to shift losses to other non-workers' compensation clients. The majority (74-89%) is unable to shift any losses to any of these entities except that 21% report that they can shift 1-25% of their losses to other non-workers' compensation clients. Table 2 shows the amount of cost shifting that is anticipated from each of the two types of pharmacies. The amount of cost-shifting they see as possible corresponds to their assessment of how negatively this will effect their business in the previous question, with those seeing the ability to cost shift, being able to protect their business viability better in the changing workers' compensation market.

Table 2:

Ability to shift losses to others: (%)					
12/19/2003 data	0%	1-25%	26-50%	51-75%	76-100%
Large Chain pharmacies:					
Drug Manufacturers	73	9		9	9
Drug Distribution Cost	75	8	8	8	
PBM/TPAs	67	25	8		
Insurance Cos.	82	18			
Other, non-WC clients	55	27			18
Independent Pharmacies					
Drug Manufacturers	82	6	7	1	3
Drug Distribution Cost	89	9.7			1.1
PBM/TPAs	76	14	5	3	2
Insurance Cos.	74	17	5	1	3
Other, non-WC clients	55	21	4	2	17

Chains also reported that with the adoption of 100% Medi-Cal pharmacy reimbursement, workers' compensation insurers and/or PBMs will negotiate discount off AWP and off the dispensing fee. However independent pharmacies reported they would be able to negotiate much less of a discount with 18% of independent pharmacies reporting unable to negotiate any discounts from PBMs/insurers. For the chain pharmacies, 36% suggested they would negotiate discounts off the AWP of 21-35%, 27% suggested that Insurer/PBM discounts would be 11-20% and another 18% each of chain pharmacies suggested 1-10% and over 40% Insurer/PBM discounts. The independent pharmacies reported discounts of 1-10% (18%), 11-20% (40%), 21-35% (14%), and 36-over 40% (10%).

Effects of mandatory use of generics: The chain pharmacies reported that they already use generic substitution either often (58%) or always (42%) with their workers' compensation clients. This is the same use as with their non-worker's compensation clients. Therefore the institution of mandatory generics will affect only a small portion of clients for which there is no generic substitution, and may have more of an effect on physicians who dispense drugs than it will have on the large chain pharmacies. However, 55% of chain pharmacies reported a decrease in profit margin of 1-10% from the initiation of mandatory generics, with 9% saying this decrease would be as much as 11-20%, 19% as much as 21-35% decrease in profits with generic use, and 27% suggesting there would be no decrease in profit margin from mandatory generics. In addition, all of the large chains reported using formularies for their non-workers' compensation clients at least sometimes, with 92% reporting using formularies often or always. For their workers' compensation patients, 33% of the chain pharmacies reported never using

formularies and 33% rarely used formularies. Since the Medi-Cal system is based on a preferred drug list (an open type of formulary), the use of formularies will have to increase for worker's compensation clients.

The independent pharmacies report less (87.3% often or always) generic substitution than did chain pharmacies (100%) for their WC patients, but more in their non-WC patients (96.1%). Also less independent pharmacies (40%) reported that mandatory use of generics would decrease their profit margin than did the chains (73%). The independent pharmacies also reported they often (44%) or always (35%) used formularies with their non-workers' compensation clients but their use was also much less than with their workers' compensation clients with 16% never using formularies, 16% rarely, 21% sometimes, and 47% often or always using formularies.

Incentive Programs to control drug prices: Table 3 shows which incentive programs are currently in use by the different types of pharmacies and which of these the pharmacies anticipate will be adopted when the 100% Medi-Cal system is initiated.

Table 3:

Incentive Programs to decrease drug costs				
12/19/2003 data	Chain Pharmacies		Independent Pharmacies	
	Current use %	Expected Adoption %	Current use %	Expected Adoption%
Monetary or Volume discounts	27	56	34	39
Formularies or Preferred drug lists	50	80	61	76
Incentives to update electronic transactions	33	56	28	42
Point of sale adjudication	80	89	65	72
Capitation PMPM based programs	100	33	8	19
Regulations to use single pharmacy	30	50	17	35
First-fill guarantees	50	70	23	41
Use of PBMs	90	90	58	65
Formal claims review/audit process	70	100	66	73

All types of pharmacies report that they expect to increase their use of various incentive programs to reduce drug costs to them although many of them are already in place. It appears that the larger pharmacy groups have the most flexibility to adopt these incentive programs, and the independent pharmacies expect less likelihood of adoption of

incentive programs. It is interesting to note that the large chain pharmacies report that they will lose the ability to provide capitation PMPM based programs with the adoption of the Medi-Cal program for workers' compensation clients (going from 100% current use to only 33% future use).

It is also interesting to note that while 50% of chain pharmacies report having first-fill guarantees, only 23% of independent pharmacies, report having these first-fill programs in place. The chains and independent pharmacies also report that they will increase this protective program up to 70% and only 41% respectively. The independent pharmacies report very low rates (17%) of incentives to encourage the use of a single pharmacy, while 30% of chains report use of such an incentive currently. In addition, 100% of chain pharmacies report that they will begin to adopt formal claims review or audit processes with the change to the 100% Medi-Cal system, although they report the lowest (70%) current use of such a program. Taking all these incentive programs into account, it is not clear how much their use will be allowed within the 100% Medi-Cal system, especially because the workers' compensation program is especially concerned about protecting access to pharmacies for their injured workers.

90% of chain pharmacies and a large number of independent pharmacies (58%) use PBMs currently. Chain pharmacies report that they don't plan to increase their use of PBMs with the advent of the 100% Medi-Cal system for drug reimbursement, however for independent pharmacies we can expect 7% more use of PBMs with the adoption of the Medi-Cal system.

Access to Pharmacy Care: Access to pharmacies in a convenient location is very important to the success of a workers' compensation pharmacy program because if injured workers are unable to obtain their drugs easily it may hinder their treatment and recovery. 42% of the chain pharmacies and 34% of independent pharmacies reported that the adoption of the 100% Medi-Cal program will severely decrease access and 25% and 32% respectively reported the change would significantly decrease access to pharmacy benefits by workers' compensation claimants. In addition 17% each of chain pharmacies reported that there would be a moderate or a slight reduction in access (16% and 11% for independent pharmacies).

42% of chain pharmacies reported that they would 'often' begin to refuse to accept workers' compensation patients if the 100% Medi-Cal system is initiated, and an additional 8% said they would always refuse patients. For independent pharmacies this anticipated refusal was stronger with 27% reporting that they would often begin to refuse workers' compensation patients and 29% said they always would. Only 8% of chain pharmacies and 10% of independent pharmacies reported that they would never refuse worker's compensation patients, and an additional 42% and 23% respectively reported that they sometimes would. 100% of the chain pharmacies indicated that for any change in reimbursement of pharmaceuticals for workers' compensation they would sometimes (25%), always (33%) or often (42%) reevaluate offering services to WC clients.

100% of chain pharmacies and 81% of independent pharmacies report that they would at least sometimes start refusing to accept WC patients with any reduction in drug reimbursement. Clearly, all pharmacies are sending the message that this drug reimbursement change will have an effect on their financial ability to accept WC patients in the future.

72% of chain pharmacies indicated that the use of PBMs in workers' compensation will reduce the number of pharmacies that injured claimants have access to. However 42% of chain pharmacies also reported that PBMs would give claimants better service and increased access either sometimes, often or always.

These responses clearly indicate that there is a potential for loss of pharmacy access for workers' compensation clients. Patient access will need to be monitored during the initiation of the Medi-Cal program to ensure that access is not adversely affected. It may be that the use of PBMs can have some moderating effect on the chains in reducing the loss to access, if their ability to adopt incentive programs reduces pricing pressures on the pharmacies. This, of course, will not have the same effect on the independent pharmacies, who generally oppose the use of PBMs because they act to reduce their profits and their business. For example more independent pharmacies (94%) than chain pharmacies (72%) report that the use of PBMs will reduce the number of pharmacies that WC clients will have access to. Finally, 67% of pharmacy chains and 62% of independent pharmacies reported that the adoption of 'first-fill' programs would act to increase access to injured workers 'often' or 'always'. Working on perfecting "first fill" programs and extending them to "all" fills until eligibility is verified or having more on-line adjudication may do the most to maintain patient access in the workers' compensation arena; aside from increasing reimbursement itself. Most comments written on the surveys describe the extra time and risk over other clients that workers' compensation patients represent to pharmacies.

Ability to re-negotiate pharmacy rates: The majority of chain pharmacies reported that they would try to negotiate new pharmacy rates with PBMs or workers' compensation insurers at least sometimes with the adoption of the 100% Medi-Cal pharmacy schedule. 83% reported that they would renegotiate rates with PBMs at least sometimes, 42% always would renegotiate with workers' compensation insurers (42% never or rarely would). The majority of chain pharmacies reported that they wouldn't or rarely would re-negotiate rates with drug manufacturers (67%) or wholesalers (58%). Therefore most of the rebate negotiations will continue to be primarily with PBMs and insurers for chain pharmacies. This picture was very different for independent pharmacies where only 13% reported that they would always negotiate new rates with PBMs, and 61% said they never or rarely would. Again independent pharmacies indicated that they also have less negotiating power than the chain pharmacies with workers' compensation insurers with 51% reporting that they never or rarely, would, or cannot, negotiate new rates with them and only 17% saying they always would. Most independent pharmacies also reported that they never or rarely would negotiate new rates with drug manufacturers or wholesalers. Of course it is logical that pharmacies who can command the most volume, also have the most ability to negotiate favorable pharmacy rates, so these data support this belief

and demonstrate again that most of the effects of these pharmacy schedule changes in workers' compensation will be felt by the independent pharmacies although the large chain pharmacies report they will be adversely affected as well.

Administrative Difficulties in Processing Pharmacy Claims: Frequently pharmacies voice concerns about the added burden workers' compensation claimants bring when filling and being reimbursed for their prescriptions. We asked about the administrative burden that these pharmacies encounter and found that the majority of chain pharmacies reported the most administrative difficulties, although independent pharmacies also reported significant difficulties. For example, 55% of chain pharmacies reported often or always having to make repeated requests for payments for their workers' compensation clients, and 73% sometimes or often had problems of incorrectly filled out paper work, with an other 18% always encountering incorrectly filled out paperwork. For independent pharmacists, 52% often or always made repeated payment requests and 78% of independents reported sometimes or often dealing with incorrect paper work. These differences may occur because chain pharmacies are seeing more workers' compensation clients or have different expectations for efficiency, or may just have fewer, though significant, difficulties administratively with the workers' compensation program. Table 4 shows these results for all three pharmacy types for all the categories of administrative problems they are likely to encounter.

Table 4:

Administrative Difficulties with Workers' Compensation pharmacy claims (%)						
Problem Type	Large Chains			Independent Pharmacies		
	Never	Rarely/ Sometimes	Often/Always	Never	Rarely/ Sometimes	Often/Always
Repeated payment requests	0	46	55	7	41	52
Incorrect paperwork	0	46	55	12	65	23
Lack compliance w/ policies	0	80	20	13	65	22
Problems w/ eligibility lists	0	46	55	7	61	32
Unnecessary forms	9	46	46	12	60	28
Rebate negotiation problems	60	40	0	44	45	12
Ineligible claims	9	55	36	11	63	26
Missing claims	0	64	36	10	66	24
Inflated claims	9	74	18	29	65	6
First fill of Rx problems	0	60	40	20	55	25

In summary, it appears that for all pharmacy types the major problem is with the difficulty of establishing the eligibility of the workers' compensation client and the associated difficulties of receiving payment even with first fill programs.

RESULTS CONT.:

Commercial Insurers and Self-Insured Providers: We also surveyed commercial insurers of workers' compensation and self-insured for workers' compensation and analyzed their results separately. 100% of the commercial insurers were doing business in all regions of California. 69% considered themselves as single line businesses, 26% as multi-line, and 5% other.

Current discounts to pharmacy payments: Currently 23%, and 27% of the commercial insurer market reported paying no reduced dispensing fees for generics or brands respectively. 61% reported reductions in generic dispensing fees of over 40% and 77% reported reductions from 1% to over 40% in generic dispensing fees. Currently there are fewer reductions in dispensing fees with the use of branded drugs in the workers' compensation market, with 73% reporting reductions of from 1% to over 40%, and 27% reporting no reductions. The majority reduction for generic dispensing fees was reported as over 40% in amount but 0-10% reductions were reported by the majority for brand dispensing fees. Current discounts from the AWP paid to pharmacies by workers' compensation for the commercial insurance market was reported to be none by 9.8 % of the market, while 31% report AWP discounts from 1-20% and 59% of the commercial insurance market reports AWP discounts of from 21 to 40%. 91% of the commercial insurers market reported that they considered that the current pharmacy reimbursement schedule for workers' compensation clients either somewhat generously or extremely generously compensates pharmacists, and only 9% of the market responded that the current pharmacy compensation was fair or under-compensating pharmacists. As we saw in the previous section, the surveyed pharmacies generally reported that the current pharmacy reimbursement rates were fair but not over-compensating them.

More Self-insured workers' compensation providers (48%) reported no reductions in dispensing fees for generic and brand drugs.

Changes with start of 100% Medi-Cal pharmacy schedule: Commercial insurers responded on 6 levels of responses to the adoption of the Medi-Cal pharmacy schedule. The majority (99%) of the commercial insurers market responded that they either strongly disagree or disagree that they will no longer plan to participate in the workers' compensation market. The insurance market also primarily indicated that they were neutral (38%) or strongly disagreed or disagreed (62%) that there would be a weaker ratio of benefits paid per employer cost.

The majority self-insured providers (89.7%) reported that they would continue to operate as a self-insured provider after the new Medi-Cal fee schedule is initiated. Reactions of the self-insured providers varied if the new Medi-Cal pharmacy fee schedule will improve their ability to cover claims with 39% reporting they agreed or strongly agreed this will improve their ability, 32% reporting a neutral response, and 20% reporting they disagree or strongly disagree that their ability to cover claims will be improved. The majority (55.8%) of self-insured providers reported that losses due to workers' compensation claims should decrease or greatly decrease due to the change to the Medi-

Cal pharmacy fee schedule, while 41% reported no change and 3.3% reported an expected increase in costs.

Lowering Premiums to Employers: Half of the commercial insurance market (50%) responded that they would be able to lower premiums to employers as a result of this pharmacy reimbursement change, with the remaining insurance market reporting that they were neutral (19%) or either strongly disagree or disagree (31%) that they will be able to lower premiums to employers. The largest percentage (51%) of the market indicated that they would expect premiums to decrease 3-5%, but 35% also thought that premiums would either increase or undergo no change. The market was fairly evenly divided in reporting that for every dollar decrease in premiums, either up to 1% or 2-5% of the decrease would be due to reductions in the costs of drug benefits because of the new legislation.

More (71.3%) of the self-insured providers than the commercial insurance market (51%) reported that workers' compensation costs will decrease due to the new legislation. 19.6% reported that they expected their workers' compensation costs to decrease by 1-2%, 21% expected a 3-5% decrease in costs, 4% expected a 6-8% decrease, 20% expected a 9-11% decrease and 7% expected as much as 12-20% decrease in costs. Responses varied from self-insured providers in reporting that for every dollar decrease in workers' compensation costs, what proportion is due to a reduction in the cost of prescription drug benefits from the new Medi-Cal pharmacy fee schedule; with 17.3% reporting they did not attribute any contribution of pharmacy reductions to overall workers' compensation costs, 23.1% reporting a 1% or less contribution, 32.7 reporting a 2-5% contribution, and 26.9% reporting a 6% or greater contribution. The self-insured providers themselves are much more removed from the actual cost information for workers' compensation than the commercial providers, primarily relying on a third party for running their programs and this may explain why their responses varies so much here.

Cost shifting: The majority (71%) of the market reported that they agreed that they could pass any loss to others with the new fee schedule. This differed when examining unweighted data where the majority were neutral (38%) and either strongly disagreed (10%) or disagreed (33%) that they would be able to pass on any losses to others. The majority of commercial insurers felt that they were not likely to have costs shifted to them as a result of the change to 100% Medi-Cal pharmacy payments. 68% reported never or rarely would costs be shifted to them from employers, 70% never or rarely would have costs shifted to them from TPAs. 45% reported that they would sometimes have costs shifted to them by PBMs however, and 15% thought this would often occur, and 20% thought it would never or rarely (20%) occur. Most also thought that it would be unlikely that cost would be shifted to them from pharmacies (50% reporting never or rarely). But 40% thought this would happen sometimes, and 10% thought it would happen often.

The self-insured providers felt less able than the commercial insurers to pass losses of f to others. The majority (54%) of the self-insured providers disagreed or strongly disagreed that they could pass off any loss, and only 9% agreed or strongly agreed that they could

shift costs. Also the majority of the self-insured (78%) reported never or rarely having costs shifted to them from other parties.

Decrease in Benefits: Finally, 59% of the commercial insurer market and 65% of the self-insured providers agreed or strongly agreed that with the new schedule that their drug benefits paid to injured workers would decrease. 36% of the commercial insurance market and 9% of the self-insured providers either disagreed or strongly disagreed with this view and 6% of the commercial insurers, and 37% of the self-insured remained neutral. The commercial insurers market primarily reported they would expect decreases in their annual benefits paid for drugs with the change to 100% Medi-Cal. 85% of the market reported they expected a decrease of 1% to 20%, with the rest of the market expecting larger decreases of up to 40%.

Program Incentives to control Costs: As can be seen by Table 5 there will not be much increase by commercial insurers in the use of incentive programs with the adoption of 100% Medi-Cal for drug reimbursement in workers' compensation. Increases are mainly seen in the future expected use of PBMs to 100%, and more expected focus expected on regulations to use single pharmacies. Also interesting is the expected loss of the ability to use several types of incentive programs with the new fee schedule that were reported by the commercial insurers. For example, the commercial market expects less use of formularies (although Medi-Cal has an existing preferred drug list), and loss of the ability to use capitated per member per month (PMPM) based programs. This may have a negative effect on the ability to control drug costs within workers' compensation. However, the increase expected use of PBMs, though already relatively high, may indicate that the commercial insurers will shift the responsibility for cost control to these entities.

Self-insured providers, on the other hand, reported that they expected to increase their use of incentive programs (Table 5). They especially reported expectations to increase the use of formularies, use of single pharmacies, and updates to their electronic transactions. The self-insured also expect to increase their use of PBMs from 60% to 68%.

Table 5:

Current incentive program use and expected adoption in %: Weighted Commercial Insurers Market and Self Insured Providers				
	Commercial Insurers		Self-Insured Providers	
Program Type:	Current use (%)	Expected Adoption (%)	Current use (%)	Expected Adoption (%)
Monetary or Volume discounts	79	99	36	48
Formularies or Preferred drug lists	97	90	39	62
Incentives to update electronic transactions	86	91	6	32
Point of sale adjudication	85	90	17	29
Capitation PMPM based programs	64	23	2	9
Regulations to use single pharmacy	10	92	22	64
First-fill guarantees	88	72	17	28
Use of PBMs	98	100	51	68
Formal claims review/audit process	93	94	62	71

Patient Access: The majority of the commercial insurance market responded that the new pharmacy reimbursement system would not decrease the number of participating pharmacies at all (70%). Another 20% of the commercial insurers market reported this decrease would be from 1%, to 5% though 3.8% felt it would be from 31-70% (see table 6). If these expectations hold true, there will be less concern about access to pharmaceutical care within the workers' compensation Medi-Cal program but still will need monitoring in the future to ensure that it doesn't decrease enough to be detrimental to workers health. It is important to note that the pharmacies reported that they anticipated much more of a negative effect on patient access than to the commercial insurers.

The effects on the workers' compensation commercial insurers market is also important, with 56% reporting that they expect changed revenues to workers compensation. In addition, most of the commercial insurers market (51%) reported that the change in

pharmacy program will change the current consolidation trend of the WC carriers, although 30% thought there would be no change in this trend.

Although the majority of the commercial insurers market felt that the use of PBMs would increase, 71% reported that this use will act to reduce the number of pharmacies that workers will have access to. The majority of the market (80%) also thought, that PBMs would not give workers' compensation claimants better service or increased access. The majority (52%) of the market also indicated that 'first fill' guarantees will sometimes, often or always act to increase access for workers' compensation pharmacy clients, although 48% reported that it rarely would. Again, just as the pharmacists reported, methods to guarantee payment for workers' compensation clients are identified as important to maintain patient access to pharmaceutical care.

The self-insured reported more expectation of reduced access than did the commercial insurers, with 30% expecting a decrease in access of 1-5% and 34% expecting a decrease of 6-30%. 8.5% of the self-insured providers expect a decrease in workers' compensation pharmacies of from 31-70%. The majority of the self-insured (59% report that the new Medi-Cal system will greatly to slightly decrease the number of workers' compensation pharmacies.

Table 6:

Access to Pharmacy care: (%)				
	% yes	Greatly/Slightly	No	Greatly/Slightly
Commercial Insurers:		Disagree	Change	Agree
Decrease WC pharmacies by 0%	70			
Decrease WC pharmacies by 1-30%	26			
Decrease WC pharmacies by 31-70%	4			
Change number of WC pharmacies		70	7	21
Change revenues to WC insurance carriers		8.5	36	56
Change consolidation trend of WC carriers		19	30	51
Change have no effect in WC market		75	17	8
Self-Insured Providers:				
Decrease WC pharmacies by 0%	27			
Decrease WC pharmacies by 1-30%	64			
Decrease WC pharmacies by 31-70%	8			
Change number of WC pharmacies		59	34	6
Change losses due to WC claims		56	41	3
Change likelihood of continuing as a self-insured WC provider		0	94	6

Effects of PBM Use: The majority (79%) of the commercial insurance market also reported that the use of PBMs will be somewhat or highly unlikely to reduce drug costs to workers' compensation providers. Only 14.3% of the market thought that the use of PBMs would be likely to reduce insurance premiums for employers, with 22% expecting no change in premiums with the use of PBMs and the rest of the market reporting it somewhat unlikely or highly unlikely for PBM use to cause a reduction in insurance premiums to employers. In addition the majority of the commercial insurance market reported that their overall profits would be unaffected by drug rebates negotiated with drug manufacturers/distributors and PBMs. This certainly, indicates a strong belief that PBMs will be unable to have much of an overall effect on the workers' compensation drug market.

The majority of the self-insured (65%) also reported that the use of PBMs will be somewhat or highly likely to help reduce drug benefit costs. However the majority of the self-insured providers reported that the use of PBMs would be somewhat or highly likely to reduce the number of pharmacies workers have access to. A majority of self-insured

providers (53.9%) also report administration difficulties at least sometimes but less often than the commercial insurers (Table 7).

Administrative Difficulties: The majority of the commercial insurers market reported administrative difficulties at least sometimes with pharmacies (78%) and secondary insurers (62%), but never or rarely reported administrative difficulties with TPAs, claim processors, PBMs, employers, or state regulators (Table 7). This probably reflects the fact that entities that have the most competitive pricing relationships having the most conflict.

Table 7:

Commercial Insurance Market and Self-Insured Providers: Frequency of administrative difficulties (%)			
	Never/Rarely	Sometimes	Often/Always
<i>Commercial Insurance Market</i>			
Pharmacies	22	76	2
Secondary Insurers	38	62	0.5
TPA/Claims Processors	62	35	2
PBMs	77	21	2
Employers/Clients	99.5	0	0.5
State Regulators	69	25	6
Self-Insured Providers:			
Pharmacies	46	35	19
Secondary Insurers	79	20	2
TPA/Claims Processors	80	14	5
PBMs	82	14	4
State Regulators	71	21	9

Table 8 demonstrates which types of administrative difficulties are experienced by the commercial insurance market and self-insured providers. In general there were few reported administrative difficulties reported. Incorrect paperwork and lack of compliance with policies and ineligible claims were the difficulties reported most frequently by commercial insurers. These difficulties are well known to the industry and deserve major focus for solutions. More attention to ‘point of service’ computerized adjudication might solve both the problems with paperwork and also the claims ineligibility if it allows instant checking of an individuals claims.

The self-insured providers primarily reported difficulties with inflated claims (41%) and making repeated payment requests (20%).

Table 8:

Administrative Difficulties with Workers' Compensation pharmacy claims:			
	Never/Rarely	Sometimes	Often/Always
Commercial Insurer Market:			
Repeated payment requests	59	40	2
Incorrect paperwork	12	85	3
Lack compliance w/ policies	16	82	2
Problems w/ eligibility lists	58	39	3
Unnecessary forms	73	24	3
Rebate negotiation problems	98	2	0.5
Ineligible claims	20	77	3
Missing claims	74	23	3
Inflated claims	46	53	0
First fill of Rx problems	62	36	2
Self-Insured Providers:			
Repeated payment requests	43	37	20
Incorrect paperwork	52	36	12
Lack compliance w/ policies	51	36	14
Problems w/ eligibility lists	69	24	7
Unnecessary forms	70	24	7
Rebate negotiation problems	95	4	2
Ineligible claims	52	37	12
Missing claims	63	28	8
Inflated claims	19	41	41
First fill of Rx problems	53	40	8

Contract negotiations: The commercial insurance market also rated certain items that could be a part of contract negotiations with PBMs as to their importance with the advent of the new 100% Medi-Cal program for payment of drugs. The ability of a PBM to maintain and update the Medi-Cal pharmacy cost structure was reported by the market to be the most important contract standard 76% of the time, while 45% of the self-insured providers reported this as the most important standard. This factor certainly seems important since many insurers who primarily insure worker's compensation clients do not have experience with the Medi-Cal system for reimbursing drugs. The use of the Medi-Cal system involves a complex software program that can determine the lowest rate to pay according to the Medi-Cal rules and update these rates monthly. Although most insurers currently don't have access to this software, gaining this access through a PBM

or other entity who already has experience with the software and payment system seems essential to launching the program by Jan 1, 2004. Also listed as important second most frequently (32% of the time), was the ability of the PBM to guarantee a network of participating pharmacies. This item was also frequently (67% of the time) listed as of secondary importance. The self-insured providers reported having established drug utilization review procedures as of second most important and as third, the ability to guarantee a network of participating pharmacies. Commercial insurers reported that having processes for generic utilization review and other utilization review programs were most often listed as of third and fourth in importance for contracts. 81% of the commercial insurers reported the ability of the PBM to disclose drug manufacturer rebate amounts as of fifth place importance, and disclosing administrative fees and value added fees as of sixth place importance to them. Seventh in importance to commercial insurers was the ability to disclose administrative fees and AWP rates on a regular basis. The majority of commercial insurers rated the ability of PBMs to have instant adjudication or point of service systems was rated in eighth place in importance, although it is not clear if this is primarily due to this being in place in many instances already or if this is truly their last concern in this list.

CONCLUSIONS:

These survey results reveal some interesting views by chain and independent pharmacies and commercial insurers of workers' compensation, on the changes in pharmaceutical reimbursement which will come into effect 1/1/2004. The following is a list of the major results and conclusions that can be drawn from these surveys:

1. Most pharmacies currently actually get paid less than the current OMFS and some much less. In addition, the independent pharmacies are currently paid much less than the chain pharmacies for workers compensation prescriptions.
2. The change to the Medi-Cal pharmacy reimbursement system will have a strong negative effect on pharmacies with the change to AWP having more of a negative effect than the change to the dispensing fee. The change to mandatory generics will have less of a negative effect on the pharmacies because they are already practicing generic substitution with their workers' compensation clients.
3. All pharmacies business viability will be negatively affected but differentially with independent pharmacies incurring the most negative effect, then small chain pharmacies, and then large chain pharmacies. Only Mail order pharmacies will possibly benefit from the change in pharmacy reimbursement.
4. All types of pharmacies report that they expect to increase their use of various incentive programs for cost reductions and efficiencies in response to the new pharmacy reimbursement system, although many of them are already in place, so their might not be much room for increase affects from these incentive programs.
5. Most pharmacies are currently using PBMs for their workers' compensation clients but don't plan to increase their use, reporting that they will act to reduce access to workers' compensation clients.
6. Chain pharmacies have a greater capacity than independent pharmacies to shift losses to others and anticipate a greater ability to re-negotiate for new rates with

- the advent of the Medi-Cal system. So again, independent pharmacies are more vulnerable to pricing pressures which will result.
7. There continue to be important administrative burdens when working with the workers' compensation system, and many of these should receive attention as they can both decrease costs to the pharmacies and act to increase access to workers' compensation clients by allowing more pharmacies to lower their cost of doing business.
 8. The affects on the commercial insurers with the new pharmacy payment system will be much less than it is on the pharmacies.
 9. The commercial insurers market currently pays significant reductions to the OMFS and reported that the current system was generous or extremely generous to pharmacists. The pharmacist disagree with this assessment and feel a much greater price pressure than do the insurers.
 10. Most of the commercial insurers plan to stay in the workers' compensation system when the new pharmacy program is started.
 11. Half of the commercial insurance market reported they would be able to lower premiums to employers as a result of the pharmacy reimbursement change and most thought this decrease could be between 3 and 5%.
 12. Most also thought that their would be from 1-20% reduction in benefits paid to injured workers with the change to the Medi-Cal system, with more anticipating even larger reductions.
 13. Commercial insurers anticipate more use of PBMs with the change to the Medi-Cal system, and may plan to use them to provide incentive programs and to navigate through the use of the Medi-Cal system. However the commercial insurers also reported that PBM use would not act to decrease drug costs. It will be important to provide contract standards for PBM contracts and to monitor the expansion of the PBM market into workers' compensation and if they act to decrease or increase drug and overall costs.
 14. Although the pharmacies thought that the new payment system would cause serious access problems and cause many of them to stop accepting workers' compensation system, the commercial insurers did not report that there would be such a decrease in participating pharmacies. Access seems to be a potential problem, at least and should be monitored with the advent of the new program.
 15. The commercial insurance market thought that the most important item for contract negotiations with PBMs is the ability of a PBM to maintain and update the Medi-Cal pharmacy cost structure and the second most important was for them to guarantee a network of participating pharmacies. Third and fourth in importance was providing generic and general utilization review. Fifth was disclosure of any rebate amounts and other fees on a regular basis.
 16. The self-insured market reported on both the advantages of reductions in worker's compensation premiums to their company and the disadvantages of the increase in drug costs and reductions in access to pharmacies that they expected from the change to the Medi-Cal fee schedule.

In summary, it appears that the new system provides too much cost pressure on the pharmacies and especially the independent pharmacies who are already functioning close

to the margin. As a result, there will likely be some decrease in patient access but it remains to be seen how much and if this will have a negative effect on workers' compensation clients, especially if maintenance of pharmacies is a strong factor in any contract negotiations with PBMs. It may be that because there are no co-pays and such a strong desire to maintain pharmacy access, that incentive programs, even through PBMs will not be able to ensure much savings over the Medi-Cal reductions in unit price. It will be important too to monitor the use and effects of PBMs on the workers' compensation market. It will also be important to monitor the health of the independent pharmacies, especially if it is thought that their viability is essential for provision of adequate patient access and if there is a strong desire to continue to have a strong positive small business environment in California. In short it might be desirable to modify the payment program, either by phasing it in more slowly, by modifying the payments amounts such as eliminating the last 5% off the payment rates, or providing some protections to the independent pharmacies.

Fee schedules throughout the Workers' Compensation System

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Due to the increasing costs of workers' compensation health care, and the increasing percentage of health costs arising from pharmaceutical care, California State Assembly bill AB 749 was passed to address the need for a new pharmaceutical fee schedule that can more effectively control the skyrocketing costs of pharmaceutical treatment in workers' compensation injuries. AB 749 requires pharmacies (but not doctor's offices, clinics or hospitals) to dispense a generic equivalent where available unless the prescribing doctor indicates otherwise, in writing. The law also requires that the Administrative Director of the Division of Workers' Compensation adopt an official pharmaceutical fee schedule by July 1, 2003 that takes this generic mandate into account, and includes a single dispensing fee, while providing reasonable access to pharmacies within a short range of the workers' home. AB 749 also authorizes employers and insurers to contract with pharmacies or PBMs (Pharmacy Benefit Management Organizations) to provide medicines and supplies to injured workers [1]. In this review, we will be focusing on a review of fee schedules and the potential impact to the state of California workers' compensation system.

Each state, several unions, the federal government and U.S. territories have workers' compensation systems, and each of these has different policies for the level of reimbursement of pharmaceutical costs to pharmacies and dispensing physicians by insurers. The equations used to calculate these reimbursement costs are what make up the "fee schedules" for workers' compensation. There is not a substantial amount of available information directly on the impact of pharmaceutical fee schedules on the Worker's Compensation in general, and not a great deal of specific information on the impact to the system in the State of California. The Worker's Compensation system for the state of California is very large, representing 18% of the U.S. workers' compensation market, and making it the largest system of workers' compensation in the world[2]. We use both direct and indirect resources to identify potential problems and resolutions with a new pharmaceutical section for the Official Medical Fee Schedule (OMFS).

We should note here, however, that a view of the worker's compensation pharmaceutical benefit alone does not necessarily give a full picture of the overall effects of change in a benefit system as a whole. Kozma et al showed in a 1990 study of Medicaid in South Carolina, that certain changes in the Medicaid pharmacy benefit system increased costs for pharmacy benefits, but decreased the incidence of hospital admission and inpatient hospital expenses [3]. We do not expect a great deal of these collateral changes with changes to the workers' compensation Official Medical Fee Schedule for pharmaceuticals, but any change in a pharmacy reimbursement system can have unexpected results, such as decrease in pharmacy reimbursement leading to a slightly increased risk of surgery [4]. It is important to consider the possibility of links between health services, and how pharmacy benefits do not stand isolated from other health care services for the injured worker. As such, it may be important to understand links between pharmaceutical treatment and other forms of treatment, especially as new payment systems evolve.

The use of Pharmacy Benefit Management Organizations to manage "carved out" (see appendix B) pharmacy benefits in Worker's Compensation should be an important

advance in cost containment for pharmacy services in workers' compensation, but there is the possibility of "cost shifting" between PBMs and insurers, who cover other forms of patient care, due to the links shown above between hospital admission and drug benefits, or surgery and drug benefits. One entity may try to shift the responsibility for treatment onto the other entity, where limiting the pharmacy reimbursement schedule would increase the risk of surgery, or something similar. It may be advisable that the Pharmacy Benefit Management organizations (PBM's) and health insurers work in close concert so as to prevent cost-shifting between the two organizations that could result in reduced patient health [3; 5]. If both the insurer and the PBM share interest in the patient receiving the best total care, there is less risk of cost-shifting incidents. Workers' compensation health benefits should ultimately be examined as a whole entity, reducing the risk of cost shifting by including the effects of changes to pharmaceutical treatment as well as other medical care.

State and Federal Workers' Compensation Prescription Fee Systems

The current California fee schedule is made up of two equations, one used to calculate reimbursement for brand name pharmaceuticals. Most fee schedule equations are made up of two parts, the "ingredient cost" or "drug cost" and the dispensing fee, the fee directly to the pharmacist (or clinic) for dispensing the drug. Most states base their ingredient cost on the Average Wholesale Price (AWP), as determined by First Data Bank, of San Mateo, California. In the California system, both the ingredient cost and dispensing fee for generic drugs is more generous than that for brand name pharmaceuticals, in order to encourage the dispensing of generic agents. Fee schedules for other states and the federal government WC system can be found in the Appendix. Generally, most other states, except for Hawaii and Idaho, have lower total costs for reimbursement, and less generous fee schedules than California.

In California:

Brand name drugs	$(AWP \times Quantity \times 1.1) + \4.00
Generic drugs	$(AWP \times Quantity \times 1.4) + \7.50

This system's goal, to promote the use of generic drugs and reduce costs, has not lived up to expectations, given that even the generous multiple of AWP and the higher dispensing fee are not necessarily enough to combat the advantages for prescribing brand name drugs, given bulk discounts to chain pharmacies or to dispensing physicians' offices. Generic substitution rates in California are at about 83%, where the generic is substituted for the corresponding brand-name agent 83% of the time such a transaction is possible. In Washington, where generic substitution is mandated by law, with no extra costly incentives, the substitution rate is 90% [6]. (more discussion on this issue in the Cost Containment Review)

The new law, AB749, has included mandatory generic substitution, unless "dispense as written" is included on the doctor's prescription. Although this change may help alleviate some of the rise in pharmaceutical costs to the WC system, it may not help in cases of physician dispensing (where physicians may prescribe and dispense brand name pharmaceuticals they have received at a discount from the manufacturer, but are

reimbursed for in full by the state), and it does not address the very generous premium on AWP that is currently used by the State of California compared to other states. AWP is a generous figure to use for reimbursement. Other systems use other benchmarks for drug cost, such as the MAC, which is the maximum allowable cost as deemed by federal programs such as Medicaid (often 90% AWP), or at the very least a discounted rate to the AWP. The other portion of the reimbursement equation is the dispensing fee to the pharmacy, which varies greatly between WC systems.

States which use a premium (a multiplier) to the AWP for reimbursing “drug cost” include California, with 110% to 140% of AWP being reimbursed for drug cost, as well as, Florida, with 120% AWP, New Mexico, with 104% of AWP, and Texas with 109% to 138% of AWP as reimbursement. Pennsylvania also reimburses at 110% of AWP, but includes no dispensing fee, so the 10% above AWP serves as the dispensing fee. States which use 100% of AWP for reimbursement include, Arizona, Colorado, Hawaii, Idaho, Kansas, Louisiana, Montana, Nevada, Utah and Wyoming, and the Federal Government WC program. States which use a discount to the AWP rate include Oregon (95% of AWP) and Washington (90% of AWP). (See Appendix for more details)

The dispensing fee is an important part of pharmacist compensation, and plays a role in the acceptance of fee schedules by pharmacists. Pharmacies make a profit both on the ingredient cost, and on the dispensing fee. The dispensing fees are used to pay pharmacists, technicians and administrative staff within the pharmacy who handle the administrative difficulties of reimbursement within the workers’ compensation system. Dispensing fees need to reimburse pharmacists and technicians for their valuable work, but some of the current state systems are more generous than necessary, and states with incentive programs to advocate generic substitution have very high dispensing fees. Dispensing fees vary widely between states, and can be a set amount, or a percentage of the prescription value (often with imposed maximum and minimum limits). The percentage rates can be very generous, for example, a prescription filled in Hawaii for 100 pills of tramadol, a generic pain reliever, can result in a dispensing fee of \$32, or 40% of the prescription, versus a state with a set dispensing fee, like Michigan, where the dispensing fee is a standard \$4. In another example, a 160mg strength pill of Oxycontin, a narcotic pain reliever, has an AWP per pill of \$16.18. In Idaho, where the fee schedule is (AWP x quantity) plus a 20% dispensing fee, the ingredient cost for a prescription of 30 pills would then be \$485.40, and the dispensing fee would be twenty percent of this, \$97.08, making for a total prescription cost of \$582.48. In Colorado, where the dispensing fee is a constant \$6.00, and the ingredient cost is the same as Idaho, the total prescription cost is \$491.40. States where the dispensing fee is a percentage of the “drug cost” most often calculate drug cost as AWP times quantity. These states include Arizona (15%), Hawaii (40%), Idaho (20%), Louisiana (brand 10%, generic 40%), and Utah (15%), and the federal government WC system has a dispensing fee of 20%. States with a constant dispensing fee include California (\$4 for brand, \$7.50 for generic), Colorado (\$6), Florida (\$4.18), Kansas (\$6), Montana (\$5.50), Michigan (\$4), Nevada (\$6), New Mexico (brand \$6.50, generic \$8.06), Oregon (\$7), Texas (brand \$4, generic \$7.5), Washington (\$4.50), and Wyoming (\$5). The “percentage” dispensing fee may act to encourage the use of higher cost drugs. It may be that unless maximum dispensing fees are set, the “percentage” system of dispensing fees can get very high, and so the

constant dispensing fees may be more effective at cost containment. The Medi-Cal system, Medicaid in California, uses a “professional” fee of \$4.05, and then subtracts a \$.50 “copay” from the overall prescription cost, making the de facto dispensing fee \$3.55. It has been estimated that the actual average dispensing cost of a prescription in California is \$6.95 [7].

Overall, given an analysis of these different fee schedules, the fee schedules with the most potential to reduce costs in the state of California include the Washington State fee schedule, the Oregon state fee schedule, and the Michigan State fee schedule. The Pennsylvania fee schedule also shows a good deal of savings to the California system, but it does not have a clear dispensing fee, as the dispensing fee and ingredient cost are lumped together as a 10% premium to AWP. The gross profit to the pharmacy is 10% above AWP, and the pharmacy itself must allocate how much of that is the result of “ingredient cost” and what is the “dispensing fee” to the pharmacist. This kind of fee schedule may prove unpopular with pharmacists, although there is no available evidence for this, it does seem that few states use a “lumped” method of reimbursement, combining ingredient cost and dispensing fee. The Medicaid fee schedule, which has been suggested as a “fix-it” for the California workers’ compensation fee schedule (pending California Senate Bill 228, Alarcon), may have the potential for a good deal of savings also, but there may be problems with implementation.

Washington	Brand: $(AWP \times QT \times 0.9) + \4.50 Generic: $(Base\ line\ price \times QT)$ or $(AWP \times QT \times 0.9) + \4.50 Generics are mandated unless “dispensing as written” on Rx
Oregon	$(AWP \times QT \times .95) + \7.00
Michigan	$(AWP \times QT) + \$4.00$
Medi-Cal (Medicaid in California)	The lower of: MAC (Max Allowable Cost) + dispensing fee $(AWP \times QT \times 0.9) + 4.05 - .50$ or FUL (federal upper limit) + dispensing fee $(negotiated\ value,\ very\ low) + 4.05 - 0.50$

Here is a sample of what kinds of costs would be associated for a single prescription:

An example of the potential changes to the California system:

Cost for 100 tablets of 50 mg Tramadol HCL, a pain reliever

System	Brand Name	Generic Name	Total Cost of Rx
Current CA system	Ultram: AWP: \$1.02 per pill		$(1.02)*100*1.1 + 4$ = \$116.20
		Tramadol: AWP: \$0.80 per pill	$(0.80)*100*1.4 + 7.50 =$ \$119.50
Oregon system with generic mandate:	N/A	Tramadol: AWP: \$0.80 per pill	$(0.80)*100*.95 + 7.00 =$ \$83.00
Michigan system with generic mandate	N/A	Tramadol: AWP: \$0.80 per pill	$(0.80)*100 + 4.00 =$ \$84.00
Washington system with generic mandate	N/A	Tramadol: AWP: \$0.80 per pill	$(0.80)*100*0.9 + 4.50 =$ \$76.50
Medicaid	N/A	Tramadol: FUL (federal allowable cost): 0.31 per pill AWP: \$0.80 per pill	$(0.31)*100 + 4.05 - .50 =$ \$34.55

Another example, this time, a brand-only drug without a FUL (Federal upper limit) price.

Cost for 100 tablets of 100 mg Celebrex (celecoxib), a pain reliever

System	Brand Name	Generic Name	Total Cost of Rx
Current CA system	Celebrex: AWP: \$1.71 per pill	N/A	$(1.71)*100*1.1 + 4$ = \$192.10
Oregon system with generic mandate:	Celebrex: AWP: \$1.71 per pill	N/A	$(1.71)*100*.95 + 7.00 =$ \$169.45
Michigan system with generic mandate	Celebrex: AWP: \$.1.71 per pill	N/A	$(1.71)*100 + 4.00 =$ \$175.00
Washington system with generic mandate	Celebrex: AWP: \$.1.71 per pill	N/A	$(1.71)*100*.9 + 4.50 =$ \$158.40
Medicaid	Celebrex: MAC: 90% AWP	N/A	$(1.71)*100*.9 + 4.05 - .50 =$ \$157.45

Yet another example, this time, a brand-only drug without a FUL (Federal upper limit) price.

Cost for 100 tablets of 80 mg Oxycontin SR (oxycodone), a pain reliever

System	Brand Name	Generic Name	Total Cost of Rx
Current CA system	Oxycontin SR: AWP: \$8.58 per pill	N/A	$(8.58) * 100 * 1.1 + 4$ = \$947.80
Oregon system with generic mandate:	Oxycontin SR: AWP: \$8.58 per pill	N/A	$(8.58) * 100 * .95 + 7.00$ = \$822.1
Michigan system with generic mandate	Oxycontin SR: AWP: \$8.58 per pill	N/A	$(8.58) * 100 + 4.00$ = \$862.00
Washington system with generic mandate	Oxycontin SR: AWP: \$8.58 per pill	N/A	$(8.58) * 100 * .9 + 4.50$ = \$776.70
Medicaid	Oxycontin SR: MAC: 90% AWP	N/A	$(8.58) * 100 * .9 + 4.05 - .50$ = \$775.75

We can see from the above examples the high cost of the current California system. For tramadol, the generic cost is higher than the brand name cost, due to the generous pricing incentives for generics, and both the brand and generic costs are \$40 more than the Washington State system. And due to the influence of the rare FUL (Federal Upper Limit) drug the Medicaid cost of this tramadol prescription is approximately one quarter of the California fee schedule cost. FUL, or federal upper limit drugs, include those drugs in the Medicaid system for which the federal government has negotiated a discount to the Average Manufacturers Price (the average price paid by wholesalers to manufacturers), in return for the guarantee of sales volume and unrestricted inclusion on the Medicaid formulary (more on this in the cost containment review). Only seven of the top 24 drugs used in workers' compensation have a FUL associated price, according to the latest Federal Upper Limit Drug List, November 2001. The number two most used drug in workers' compensation, Celebrex, does not have a FUL price or a generic available, and we can still see dramatic savings (\$35) with the use of the Washington State system, and here the Washington State and Medicaid system are very similar in the degree of savings. With a very expensive drug, such as Oxycontin SR (one of the most popular throughout the workers' compensation system), we see a savings of close to \$172 between the Medicaid fee system and the previous California OMFS fee schedule.

The following chart is a summary of the percent savings over the current California system for the top 24 drugs used in workers compensation[1], assuming that 100 pills are being dispensed at a prescription, as in the above tramadol and Celebrex examples. This allows us to judge the potential affects of both the ingredient cost as well as the dispensing fee changes. We also assume for these estimates that the generic mandate will be followed, and that if a generic is available, it will be substituted.

Average Savings to California System for Top 24 WC drugs (with a Rx of 100 pills)

	Oregon vs CA	Michigan vs CA	Washington vs CA	WSIA vs CA	Medi-Cal vs CA
Range of Average savings	19.4-19.8%	16.7-17.0%	24.7-24.8%	26.5-26.6%	34.4-38.4%
Standard deviation	8.60%	9.70%	8.60%	7.40%	25.50%

Although the Medi-Cal system seems very attractive here, with a savings approaching 35% over the current California workers’ compensation system, it may be more difficult to implement the full Medi-Cal system within workers’ compensation. In addition, if the Medi-Cal rates are accepted as a replacement for the current California system, a two year phase-in program may be advisable as a gradual introduction to this new, significantly reduced fee schedule. This issue will be addressed more thoroughly in the Access review. It may not be possible for the workers’ compensation system, for example, to use the federal FUL drug prices in a state workers’ compensation program, since they have been negotiated by the federal government for use only in Medicaid. In addition it may be difficult for the workers’ compensation system administratively to negotiate rebates for admission to a formulary, as the California does, unless they use a PBM. The Medicaid system and the Washington State Worker’s Compensation system are almost equivalent in savings if the FUL prices and rebate prices cannot be used. Therefore SB 228 may be mandating a schedule similar to the Washington State Worker’s Compensation system which currently has demonstrated no problems with access.

The Commission of Health and Safety in Workers’ Compensation 2000 study

The main study available focusing on the potential impact of changes to the Worker’s Compensation OMFS pharmaceutical fee schedule is a UC Berkeley study, “Study of the Cost of Pharmaceuticals in Worker’s Compensation” [6]. According to this extensive study, reimbursement under the OMFS is higher than many other states’ workers’ compensation systems, or other regulatory systems, such as Medi-Cal, the Veterans Administration, or private payer contracts (HMO’s, PPO’s, non-occupational insurance). It is possible that costs for the WC system are between 50 and 100 percent higher than group health patients for the same treatment.

A large data set was obtained from the California Workers’ Compensation Institute (CWCI) for this study, representing 20% of WC cases for the 1998-99 year. It is estimated that the total California WC Pharmacy costs will top \$297 million in 2003, accounting for 6.7% of total WC medical costs. There may be some problems with these estimates, due to the inclusion of medical management costs. Some of these costs are unavoidable, due to more workers in the state, increased treatment with drugs, increases in underlying wholesale drug costs and a changing set of drugs used in the treatment of worker injuries. Given the limits placed on the California Workers’ Compensation system, it is a challenge to discover methods of cost savings on pharmaceuticals. A review of cost containment and incentive policies is covered in another review.

The study analyzed the fee schedules listed in the appendix, and compared them to the California fee schedule. It was found that the Washington state workers’ compensation system had the most savings over the current California OMFS, with a 23% savings, followed by Pennsylvania and Michigan (13% savings) and Oregon (11%

savings). The study also compared the workers' compensation fee schedules to certain private insurers (specifically the Washington Self Insured Association, WSIA) and Medicaid in California, Medi-Cal. They also analyzed the effectiveness of generic substitution programs, and they found that Washington State, with its generic mandate, had the highest generic substitution rate, even though California (and other states) had generic incentive plans for pharmacists. The Washington system was more effective at achieving generic substitution, with 40% less ingredient costs and 36% less dispensing costs. The results of this part of the Berkeley study have been used to justify the generic mandate written into AB 749, and there are high hopes for its ability to reduce costs in California workers' compensation.

In its conclusions, the Berkeley study estimates that employers are pay 40-45% more for pharmacy costs than appears necessary due to the generosity of the current fee schedule. The Berkeley report suggests using a discount to the AWP, as the Oregon and Washington State workers' compensation systems already use. This report also goes on to discuss other cost control measures, and the importance of negotiating power in the ability to reduce fee schedule associated costs.

Negotiating Power

Much of the successful cost containment in pharmaceutical therapy has resulted from negotiations with drug manufacturers and wholesalers trading a guaranteed sales volume in exchange for price reduction. The federal government, large insurers, HMOs and PBM organizations have taken advantage of this relationship. The California Worker's Compensation system, and other state workers' compensation systems, all suffer from an inability to take advantage of the large scale negotiating power of federal organizations such as the Department of Veterans Affairs, Medicaid or Medicare. In the private sector, pharmaceutical benefit management organizations, PBMs, have made their impact felt throughout the insurance industry with their ability to negotiate rebates from drug manufacturers in return for the large market share of the organization. The state-by-state nature of the workers' compensation system prevents the WC system from having the negotiating power or congressional mandate of the federal systems, or the economic clout of private insurers or PBMs. As such, all of the state systems have reimbursement rates more generous than either the federally controlled systems, or private payer insurance. Although approximately 14 million workers are covered by California workers' compensation law (<http://www.cwci.org/faq>), the WC system is a deregulated system with a wide array of companies offering workers' compensation insurance coverage, and so, on their own, none of these companies have the negotiating ability to reduce reimbursement rates to pharmacies or to negotiate rebates from drug manufactures, which PBMs and large private payer insurers can do for health insurance. AB749 allows workers' compensation insurers to begin a negotiating process to reduce pharmaceutical reimbursement rates and contract with PBMs and/or network pharmacies. This is an important step in cost control, which will be covered more in the Cost Containment Review.

There are several examples of federal agencies using their volume to negotiate rebates or discounts on drug prices. Medicaid is one such system. Medi-Cal (Medicaid), has federally mandated rebates (the FUL system) and a guarantee of "best

price” [8]. Medicaid programs can mandate “ethical” drug firms to rebate at least 15% of the state’s expenditures for all drugs to the state Medicaid programs agencies for Medicaid-reimbursable prescription drugs [9]. Even Medicaid systems have begun to employ PBM companies to manage pharmacy benefits, which has been done in Georgia [10]. Members of the California Senate have suggested immediately moving to the Medi-Cal (Medicaid) fee schedule for workers’ compensation in California, and there is a bill currently in the California senate to mandate such (SB 228 Alarcon). But the state may have to enter its one negotiation rounds and implement a formulary in order to completely replicate the Medicaid fee schedule, including the FUL rates. Medicaid and Medicare will be discussed in more detail in a related review.

For the VA, DOD, and Public Health Department, federal law states that drug manufacturers must sell at a minimum of a 24% discount to the best prices negotiated with other buyers [11]. This can mean a total discount of 40 to 50% below the AWP, the average wholesale price which manufacturers recommend that wholesalers charge retailers [12].

For group health insurers using a Pharmacy Benefit Management Organization, drugs are typically reimbursed at 12 to 13% below AWP [5]. This savings is multiplied by the private insurers’ and PBMs’ ability to negotiate rebates from drug manufacturers in return for the insurer’s buying power guaranteeing a certain market share. The negotiated discount combined with the rebates from drug manufacturers have been estimated to as large as a 55% discount off AWP. Private insurers also negotiate some of the lowest dispensing fees, on the order of \$2.35 to \$2.40.

The state workers’ compensation system with the lowest drug costs is the Washington state workers’ compensation system. However, it may not be possible to completely replicate this system in a large, low regulation system such as that in California. Unlike other states, Washington State can engage in some negotiation, due to the monopoly-like system of health insurance for Worker’s Compensation in that state (the Washington Self Insurance Association). Washington State is cited by the UC Berkeley study [6] as a goal to reach for in cost-containment, but the same level of cost savings (23% lower reimbursement costs by fee schedule that California) may not to be able to be reached in a diverse, lesser-regulated state such as California. In addition, it may be difficult for the California system to change and adopt all of the potentially useful cost containment policies in one stage. As an intermediary cost saving step, the generic mandate combined with a system such as that of Oregon (95% AWP x quantity + \$7.00) or Michigan (AWP x quantity + \$4.00), which also show a cost improvement of over 10% versus the California system, might be more desirable.

It is in the interest of California to use some of the negotiating power available to PBM organizations for the benefit of employers paying workers’ compensation premiums, and so AB749 has opened up the workers’ compensation marketplace to allow insurers to contract with PBMs and network pharmacies for pharmaceutical discounts. This type of system has helped Washington State’s WSIA insurer to pay an average of only 64% of the California Fee Schedule rate for most pharmaceuticals [6]. Although the California system is deregulated, with a large number of workers’ compensation insurers, increasing the number of PBM organizations involved with workers’ compensation insurers would allow insurers and employers to obtain some of the level of cost containment seen by the Washington State WSIA insurer. PBMs can effectively use

negotiate power to lower drug costs. It is important to put proper controls on the PBM organizations, and mandate that rebates be returned to the insurer (more such controls are dealt with in the Contracting review), but overall PBMs can help achieve a high level of savings by guaranteeing drug manufacturers a sales volume.

Conclusions

The current California Workers' Compensation fee schedule for pharmaceuticals is one of the most costly in the nation. Due to the need for cost containment, a new fee schedule is desired. This new fee schedule needs to balance the need for wide access to pharmaceuticals (see Access review), and the need for effective cost containment (see Cost Containment review). Our current recommendation for an initial pharmaceutical fee schedule change would be to combine a mandate for generic substitution with a fee schedule successfully used in a state such as Washington, Michigan or Oregon, which all have more than 10% savings on average drug reimbursement costs, as compared to the current California pharmaceutical fee schedule. Combining this type of fee schedule with other cost containment policies through the use of the negotiating power of PBMs should achieve the kind of necessary cost containment in the pharmaceutical benefit sector of workers' compensation, without disrupting access to drugs for workers' compensation patients.

Another suggested fee schedule is the adoption of the Medi-Cal fee schedule. The state may not be able to easily replicate the FUL (federal upper limit) rates, which apply to about 25% of drugs used in workers' compensation, and are substantial discounts to any wholesale price. Replicating these rates would likely require the state to enter into negotiations with drug companies and wholesalers to set up a system similar to the FUL system, and such negotiations would likely take time and money, not to mention a new state-wide office. In the Medicaid system, the other 75% of drugs used in workers' compensation would be priced at the MAC (maximum allowable cost) level, which is typically 90% of AWP (but slightly lower for some agents). This number, 90% of AWP, is the same ingredient cost as the Washington State workers' compensation system. The best solution may be to adopt the Medi-Cal system of 90% of AWP for all drugs, and then adopt contractual standards that would allow a single PBM system or each individual insurer or self-insured employer to set up their formulary or prior approval drug list, and negotiate with drug companies directly to obtain volume discounts for drugs, as the federal and state governments do for the Medicaid program. This process would eliminate the need for a state-wide office to negotiate discounts such as the FUL and MAC prices for all of the workers' compensation insurance system.

Appendix: A

Listing of Fee Schedules (adapted from Neuhauser et al) [6] (ingredient cost followed by dispensing fee)

State/Government	Fee Schedule for Pharmaceuticals
Alaska	Use NDC: Fee x QT (quantity) if NDC not found use average retail pricing database at 90%
Arizona	(AWP x QT) + 15%
California	Brand name: (AWP x QT x 1.1) + \$4.00 Generics: (AWP x QT x 1.4) + \$7.50
Colorado	(AWP x QT) + \$6.00
Florida	(AWP x QT x 1.2) + \$4.18
Hawaii	(AWP x QT) + 40%
Idaho	(AWP x QT) + 20%
Kansas	(AWP x QT) + \$6.00
Louisiana	Brand: (AWP x QT) + 10% Generic: (AWP x QT) + 40%
Medi-Cal (Medicaid in California)	The lower of: MAC (Max Allowable Cost) + dispensing fee (AWP x QT x 0.9) + 4.05 - .50 or FUL (federal upper limit) + dispensing fee (negotiated value, very low) + 4.05 - 0.50
Michigan	(AWP x QT) + \$4.00
Montana	(AWP x QT) + \$5.50
Nevada	(AWP x QT) + \$6.00
New Mexico	Brand: (AWP x QT x 1.04) + \$6.50 Generic (AWP x QT x 1.04) + \$8.06
Oregon	(AWP x QT x .95) + \$7.00
Pennsylvania	(AWP x QT x 1.1)
United States Federal Workers	(AWP x QT) + 20% (min dispensing fee \$2.50, max \$15.00)
Utah	(AWP x QT) + 15%
Texas	Brand: (AWP x QT x 1.09) + \$4.00 Generic: (AWP x QT x 1.38) + \$7.50
Washington	Brand: (AWP x QT x 0.9) + \$4.50 Generic: (Base line price x QT) or (AWP x QT x 0.9) + \$4.50 Generics are mandated unless "dispensing as written" on Rx
Wyoming	(AWP x QT) + \$5.00

Appendix B

Flow Chart of Billed and Paid Transactions for Pharmacy Services

There is a complex web (see diagram 1 and 2) of outsourcing service companies and sub-specialists employed to administrate pharmacy benefits under the California workers' compensation system. Commercial insurance companies and self-insured organizations will outsource to third party administrators (TPA) to process complicated medical claims only to have the TPA outsource to a specialist in pharmacy billing and drug review, commonly referred to as a pharmacy benefit management (PBM) company. Commercial insurance companies and self-insured organizations may themselves contract with a pharmacy benefit management (PBM) company to administer pharmacy benefits directly with the employees covered.

The pharmacist fills the prescription for the injured worker and directly bills the workers' compensation insurer or the designated pharmacy benefit management (PBM) company. Depending on the entity administering the pharmacy benefits for the injured worker the transaction with the pharmacist may be paper-based or processed with a electronic "point of sale" (POS) system for instant adjudication. The level of automation used to process transactions for pharmacy services covers a broad spectrum and depends on the individual organization and that company's level of automation.

The pharmacy benefit management company or a third party administration service will in most cases, "pass-through" the charges for the pharmacy transaction directly to the commercial insurance company or the self-insured employer. There will be an administrative fee for processing the individual transaction. The bill will include and ingredient cost for the prescription and a dispensing fee for the pharmacist's service. The amount billed to the insurer or self-insured employer may not be the same amount paid to the pharmacist by the pharmacy benefit management company. In some cases, the pharmaceutical manufacturer may offer financial discounts directly to the pharmacy benefit management company as an incentive to include a specific drug on the formulary list or for volume sales. Depending on the contract, this rebate may not be shared with the client, the commercial insurance company or the self-insured employer.

Diagram 1

Billed Amounts

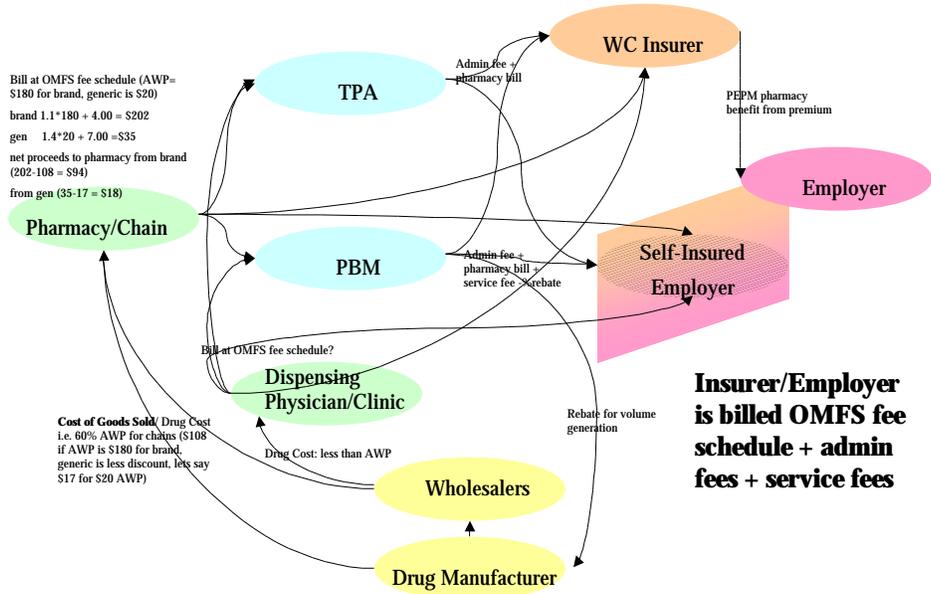
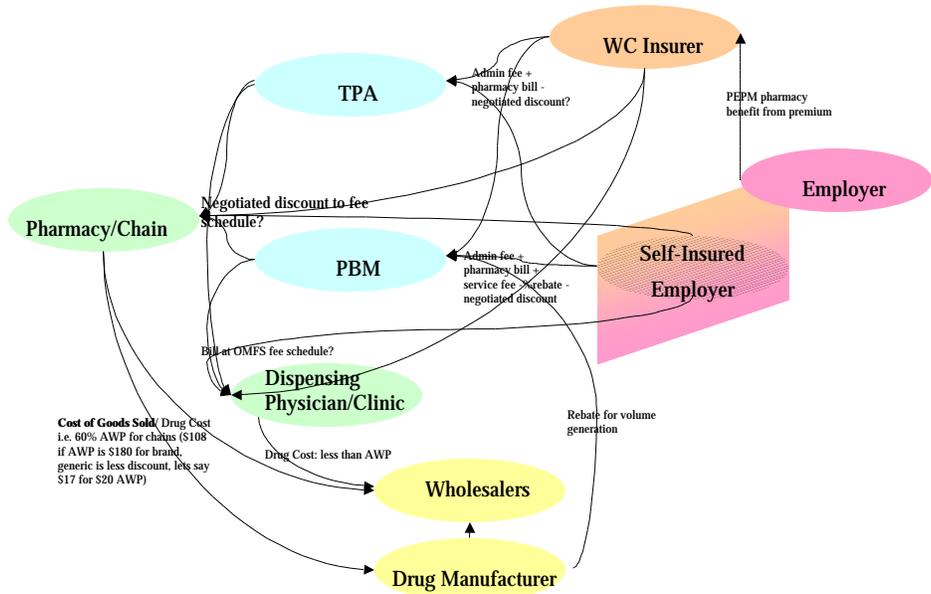


Diagram 2

Paid Amounts



References

1. CWCI. 2002. Pharmaceutical Cost Management in California Workers' Compensation, Pharmaceutical Cost Management in California Workers' Compensation. California Workers' Compensation Institute, Oakland, CA, pp. 1-13
2. Blay, N., N. Smithline and A. Swedlow. The integration movement in California's workers' compensation market *J Ambul Care Manage* 23 (3):57-69, 2000
3. Kozma, C. M., C. E. Reeder and E. W. Lingle. Expanding Medicaid drug formulary coverage. Effects on utilization of related services *Med Care* 28 (10):963-77, 1990
4. Reutzel, T. J. The nature and consequences of policies intended to contain costs in outpatient drug insurance programs *Clin Ther* 15 (4):752-64, 1993
5. Lipton, H. L., D. H. Kreling, T. Collins and K. C. Hertz. Pharmacy benefit management companies: dimensions of performance *Annu Rev Public Health* 20:361-401, 1999
6. Neuhauser, F., A. Swedlow, L. Gardner and E. Edlesten. 2000. Study of the Cost of Pharmaceuticals in Workers' Compensation, Study of the Cost of Pharmaceuticals in Workers' Compensation. Commission on Health and Safety and Workers' Compensation, Oakland, CA, pp. 1-38
7. 2002. State Finally Releases Legally Required Report Regarding the Medi-Cal Pharmacy Cost of Dispensing Prescription, State Finally Releases Legally Required Report Regarding the Medi-Cal Pharmacy Cost of Dispensing Prescription
8. Shulman, S. R. The reimbursement factor in pharmaceutical regulation: rebates, cost-effectiveness, and practice guidelines *Pharmacoeconomics* 1 (Suppl 1):21-7, 1992
9. Okunade, A. A. Financing structure dynamics and other determinants of Medicaid pharmaceutical expenditures, 1993-1996 *J Health Care Finance* 25 (1):59-71, 1998
10. Bae, J. P. and P. G. Justice. Pharmacy benefit management contracting: an assessment from a recent public sector procurement experience *J Health Care Finance* 29 (1):49-56, 2002
11. Iglehart, J. K. Medicare and drug pricing *N Engl J Med* 348 (16):1590-7, 2003
12. Russell, L. B. and N. Wolff. The impact of drug pricing policies on the health of the elderly *Am J Prev Med* 22 (3):151-5, 2002

Cost Containment Incentives in Workers' Compensation

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The workers' compensation system in the state of California is in need of cost containment procedures. Pharmaceutical expenditures have consistently risen with the increased cost of drugs and their increased use in therapy for the injuries common in workers' compensation cases. Workers' compensation insurance premiums have nearly doubled in the past three years, according to David Bellusci of the Workers' Compensation Insurance Rating Bureau, partly to make up for a period in the mid-to-late nineties where companies fought a price war on premiums and were taking a 140% loss on premiums for payouts to claimants [1]. Workers' compensation costs are still increasing, where it is estimated that it costs 25% more in the WC system to treat the same injury it would in the group health insurance system [1]. It is estimated that 6.5% of all medical costs in workers' compensation are pharmacy costs, and that number is increasing every year, from less than 4% of medical costs in 1996 to an estimated 7.3% of costs (\$375 million) by 2005. This represents a 12% growth rate in the underlying costs for drugs prescribed in workers' compensation in California [2], between 1998 and 1999. This is not as high as the increase in drug prices nationally in the years 2001 to 2002, where the rate of increase in drug spending rose close to 20%, according to the 2002 Segal Health Plan Cost Trend Survey (<http://www.segalco.com/publications/surveysandstudies/2002trendsurvey.pdf>).

AB749 and SB228 are laws designed to help control certain aspects of workers' compensation expenditures [3]. We focus in this review on those parts of the laws which are targeted toward reducing the costs of pharmaceutical therapy. Included in this law is the mandate for the use of generic medications if a generic is available, the creation of a new pharmaceutical fee schedule (which is "100% of the Medi-Cal fee schedule") for cost management, and the laws also allow employers and insurers the ability to negotiate with network pharmacies and contract with Pharmaceutical Benefit Management (PBM) companies to arrive at pharmaceutical cost structures and create incentives to contain the costs of pharmacy. PBMs can also use a variety of incentive systems to hold down the cost of pharmaceuticals. Given these new mandates, there is now a wide array of techniques and incentives, in addition to a less generous fee schedule, that could be used for cost containment of pharmaceuticals.

Incentives

Both demand-side and supply-side incentives have been used in both public and private health insurance systems as a method to cut costs. According to an Ellis and McGuire paper in 1990, "Any health payment system consists of two parts: the insurance system that structures patients' incentives to demand care, and the reimbursement system that structures providers' incentives to supply care [4]." There are pros and cons to focusing on either the demand side (what care patients or physicians demand) or the supply side (what providers are willing to give).

Demand-side incentives are incentives that encourage patients to limit their demand for services from the health care system, and consist of cost-sharing approaches, such as patient co-pays, co-insurance, deductibles and benefit caps. In the world of

pharmaceutical benefits, if overly strict, these methods may lead to issues of under-utilization by patients, a serious concern [5]. For the worker's compensation system in California, the demand-side incentives (or dis-incentives) for patients currently consist only of the legal requirements involved in proving the claim that injury occurred on the job; no co-pays or co-insurance can be mandated for workers' compensation patients [2]. In other words, incentives which would encourage patients to limit their demand for pharmaceutical services, are not allowed to be used in the workers' compensation system. Therefore, when discussing methods to contain drug costs, it is necessary to focus mostly on supply-side mechanisms when changing the pharmaceutical fee schedule to arrive at cost savings. It may be possible within the Medi-Cal fee structure to provide demand incentives to physicians however, such as drug treatment guidelines.

Supply-side incentives are those that encourage health care service providers to limit how much service they can provide, or how it is provided, and include incentives to physicians and pharmacists to alter prescribing and prescription filling habits in order to fall in line with cost-saving methods and good standards of practice. These measures can include altered dispensing fees, which have already been used in California worker's compensation (reflected in the previous fee schedule equation), to encourage generic substitution. Other incentives include formularies (or other kinds of limited drug lists), physician drug detailing, and restrictions on provider change or provider choice, and drug utilization review. In the previous California workers' compensation pharmaceutical fee schedule, different reimbursement is offered for brand name pharmaceutical versus generic pharmaceuticals, whereby generic pharmaceuticals are reimbursed at a more generous rate of markup to the cost of the ingredient (drug cost), as well as a higher dispensing fee paid to the pharmacist for performing the generic substitution. Mandatory substitution, which will be introduced with the enactment of the new fee schedule for pharmaceuticals, as per AB 749 in July (or November) 2003, is another kind of supply-side incentive that could be used effectively within the California workers' compensation system. Other supply-side incentives can be found throughout literature resources, and are already in use in other insurance systems and will be discussed below, along with generic mandates.

Integration and Pharmaceutical Benefit Management Organizations

Integration in the workers' compensation market means the incorporation of managed care principles into the workers' compensation system, and the co-operation between group health plans and workers' compensation insurance, to take advantage of the medical resources of group health programs or managed care programs, most of which are supply-side incentives. These efforts have not had the successes promised in the early 1990's, and many pilot projects have failed, often due to the constraints on the workers' compensation system to limit patient's ability to change providers [1], and the difficulties matching claims cycles between group health and workers' compensation insurers. However, one program showing a good deal of success is the Alliance project developed by Kaiser Permanente, the state's largest health maintenance organization, and the State Compensation Insurance Fund, the state's largest workers' compensation carrier [1]. This partnership has seen some success with a four-year pilot completed in 1999 that showed a 16% reduction in the total costs for all medical claims. Injured workers were

directed into one of Kaiser's occupational health clinics, where physicians experienced with the workers' compensation system and with treating these kinds of injuries could give the best of care. Another integration project is underway between SCIF and a major pharmaceutical benefit management organization (PBM). SCIF has contracted with Express Scripts, one of the largest PBM organizations, since November 1999, and have had success implementing a pilot program in the San Diego and Fresno claims offices (<http://www.scif.com/products/claims/express-scripts.htm>). These integration success stories illustrate the benefits of scale and expertise, and how the negotiating and organization expertise of companies like Kaiser and Express Scripts could help with cost containment efforts, and provide a model for future contracts. PBMs especially should be able to help implement a variety of cost containment incentives, without additional cost to the state or to employers.

Generic Mandate

There is an array of other supply-side incentives that have been used in other health care systems, many of which are highly specific to pharmaceutical care. A very important cost control measure is already scheduled within the workers' compensation system, as per AB 749, and that is the mandate for generic substitution, unless "Dispense as Written" is written on the prescription. Generic substitution is the requirement that the pharmacist substitute an available generic drug for the brand name equivalent, if a generic is available, and the physician has not countermanded the mandate. SB 228 has extended this rule to include all providers of pharmaceutical care, including clinics and prescribing physicians. Generic drugs are usually significantly less expensive than brand name or single-source counterparts, and so significant cost savings may be possible with an increased level of generic substitution. Previously, generic substitution was encouraged in the California workers' compensation system through a program of generous (and expensive) incentives to the pharmacist for implementing generic substitution, including higher reimbursement for ingredient cost, and a higher dispensing fee. The rate of generic substitution in California was therefore 83% in 2000, but the rate of substitution in Washington State, which did not have generous incentives, but did have a generic mandate, was 90%, a good deal higher [2]. Possible reasons for this have been postulated, including the incentives not being enough to make up for the difference in profit margin for the pharmacy between brand and generic drugs, and the administrative difficulties for the pharmacy in calling the doctor to approve a generic substitution. As such, the generic mandate is part of AB749 and SB228, and a key recommendation in the CHWSC commission report in 2000 [2], in order to reduce costs associated with the generous incentive program.

Other agencies have reported varying levels of success with a generic mandate, and although it is an important step in pharmaceutical cost control, it may not be enough to cause a significant change either in the rates of substitution, or in the total cost of pharmaceutical products to the workers' compensation system. In the public drug reimbursement system in Australia, there has been success in lowering costs and increasing the amount of generic drugs being dispensed with the generic substitution enforced with a Minimum Pricing Policy (a form of reference drug pricing) [6]. The Minimum Pricing Policy (MPP) in the Pharmaceutical Benefits Scheme in Australia sets

the government subsidy for a drug at the level of the lowest priced brand (including generics). Generic substitution in Australia was not easily accessible to pharmacists until a change in law in 1994, and so before that, patients had to make up the cost for the brand name drugs prescribed by their doctors. After December 1994, generic substitution became much simpler in Australia, and with the enforced MPP program, there was a considerable incentive for generic substitution, and the rates of generic substitution rose from 17% to 45%. Fixed pricing is not legal here in the US, and therefore the use of generic mandates replace the incentive of the MPP policy in Australia. Carroll et al did a review of Drug Product Selection (DPS) laws in the United States (mostly with Medicaid systems, but some private insurers), and came up with a list of characteristics of programs, which had the most success with implementing generic substitution. Generic substitution was higher in states that: 1) did not require additional record keeping due to the substitution 2) required patient consent for the substitution 3) used one line prescription forms 4) had mandatory product substitution laws 5) had formulary restrictions and 6) had laws that did not contain language designed to limit pharmacists' liability [7]. Anis et al found that in Canadian provinces where substitution is mandatory, more physicians write a "No Substitution" clause on the prescription form, because they feel that brand name products are being unfairly treated.

The most success with generic substitution was seen in provinces that required increased paperwork on the part of the pharmacist for not using generic substitution and provinces that required that patient's be asked their approval, rather than provinces which mandated automatic generic substitution [8]. The design of prescription pads is important, and if simply crossing off a box on the pad can prevent generic substitution, often the physician does just that, preventing the pharmacist from substituting a cheaper generic for the brand. Often, these preprinted prescription pads are provided free of charge by drug companies. Mott et al conclude that pharmacists play the key role in promoting generic drug use, and that efforts to increase generic substitution should be targeted at them, followed by increased efforts to educate prescribers [9]. In the generic mandate scenario going into effect in California, this situation is reversed, and the prescriber has a good deal more power over substitution conditions, with the "Dispense as Written" designation. With a generic mandate, as opposed to generic substitution, the emphasis for generic substitution is taken off the pharmacist, who must follow the law and substitute with the generic, and the responsibility for choice of brand over generic is placed upon the physician, who has the right to require the use of the brand name drug. The current California plan of mandating generic substitution might also benefit from implementing some of the characteristics seen in the Carroll et al study, including keeping paperwork to a minimum by not requiring any additional forms to be submitted in order to substitute with a generic (but may require doctors to submit a form of why **not** to substitute with a generic), implementing a formulary which will encourage the most cost-effective standard of care for the patient, and using one line prescription forms which will make it a little more difficult for physicians to automatically prevent generic substitution. It is estimated that increasing generic substitution ten percentage points in California, from 83% to 93%, would reduce costs for pharmaceuticals in the workers' compensation system by 2.5% [2].

Alternative Pricing for Ingredient Cost

Another cost containment strategy used by other agencies and other countries is using an alternative to the current “AWP” system of reimbursement for ingredient cost. AWP stands for average wholesale price, the price defined as the amount of money the pharmaceutical company says it costs to produce the drug plus a 15 to 20 percent mark-up (www.hrsa.gov/odpp). Straight AWP may be a very generous amount to estimate the actual ingredient cost to pharmacies and dispensaries, which often negotiate substantial discounts to the official AWP with manufacturers [2]. Many systems, including state workers’ compensation, Medicaid, and private health insurers use AWP times a multiplier to calculate the “ingredient cost” to reimburse pharmacists. AWP is not a bad basis to calculate drug cost, but the multiplier is currently very high in the California workers’ compensation system, at 110% of AWP for brand name drugs, and 140% for generics. Medicaid tends to use a multiplier of 90% of AWP for many drugs (those not covered by a negotiated special price), as does the Washington state workers’ compensation system. An alternate multiplier of AWP (the Medicaid multiplier) has been recommended for the California system by the CHSWC commission in order to cut excess costs, and this is a simple, viable method of cost containment in workers’ compensation in California. Our review of the Fee Schedule goes into more detail regarding AWP pricing, and demonstrates the effects of different multipliers of AWP pricing on drugs commonly used in workers’ compensation.

Medicaid uses a fee system incorporating the lowest of three options. One option is the fee equation “AWP-10%”; another is the state “MAC” or “MAIC”, maximum allowable cost, which is a state negotiated price, usually also a fraction of AWP, usually 90%, for a majority of drugs used in that system; the last option, not available for all drugs, is the FUL price, or Federal Upper Limit price, which is a federally negotiated (by the HCFA) price, often significantly lower than the other two options. Other large, federal government systems use this complex system of negotiated discounts for some drug services to the poor or underserved populations, such as those served by Medicaid, the Veteran’s Affairs Administration, the Bureau of Indian Affairs and the Department of Public Health. These special negotiated discounts, such as the FUL, involve a significant rebate to the Average Manufacturer Price (AMP, the average price manufacturers sell to wholesalers over a given time period), and are often significantly lower than any wholesale or retail price available (www.hrsa.gov/odpp). According to a 1990 law, pharmaceutical companies interested in this government program refund state Medicaid programs with the difference between the price of a drug charged to Medicaid and the lower of the average charged for the product, less 12.5% (10% for generics), or the lowest price for that drug dispensed to any insurer or purchaser in the state. In return, they gain unrestricted access to the Medicaid formularies in that state [10]. These programs are dependent on the participation of drug manufacturers, and the guaranteed volume available to the manufacturers based on the inclusion on positive drug lists, or “contract drug lists”, without the need for prior approval. It required a federal law, OBRA 1990 in order to enact this program.

In the case of drugs used for workers’ compensation, only about one quarter of the most commonly used pharmaceuticals have corresponding FUL rates, and many of the most common drugs, such as Oxycontin, Celebrex and Vioxx, are instead reimbursed

using the AWP-10% equation. Those drugs which do use these AMP prices, however, are calculated specifically for each wholesaler and are proprietary. Therefore it is difficult to know what effect AMP specific to use in a workers' compensation system would be. It is unlikely that the DIR administration would want to negotiate their own rebates off AMP or maintain an AMP discounted list themselves. The degree of discount found in the AMP rates might be difficult to achieve by a deregulated (non-monopoly, decentralized) state workers' compensation system, even in a state as large as California. The state would most likely need to negotiate these discounts on a large scale, as does the federal government, and guarantee participating manufacturers sales volume using a formulary system. Using PBMs to perform this service on an insurer level, rather than at a state- wide level, is another option to achieve substantial savings, i.e. each insurer or PBM can negotiate their own rebates.

Profit Regulation

Cost control methods like profit regulation, fixed profit margin for wholesalers and retailers, and reference-based pricing are often used in Europe [10; 11]. Profit regulation and fixed profit margins control how much profit the drug manufacturer can make on the drug, in order to pay for research and development costs. Reference-based pricing, in its most strict form, involves fixing the price of all agents within a therapeutic class to be the same as the lowest cost member of the drug class. These methods include intensive government intervention and are mostly used only by European countries. However, reference pricing is an interesting model to examine, although reference pricing has legal implications here due to our limits on price fixing, which Europe doesn't have.

In reference-based pricing, all the members of a therapeutic class of drugs are considered to be "therapeutically equivalent", even though there is much debate over the scientific merits of these assumptions. As such, all of the drugs in the assigned class are reimbursed at the lowest price available for any of the therapeutic agents in the drug class [12]. These policies have been used in Europe and some provinces in Canada, to mixed reviews. Although in the U.S., the strict price controls used in Europe are not available, HMOs, PBMs and large purchasing groups manage to negotiate considerable discounts to what are the highest drug costs in the industrialized world [10], paying on the order of 55% of Average Wholesale Price, after rebates and discounts are taken into account [2]. Discounts to AWP for ingredient cost, accompanied by an increased role for PBM companies' negotiating power, may be the simplest, most effective solution for the California workers' compensation system, as discussed in more detail in the Fee Schedule Review.

Formularies, Contract Drug List, Prior Approval Lists, and Therapeutic Guidelines

Controlling the cost of drugs through formularies is a very popular option in use throughout private health insurance, and many states' Medicaid programs. Formularies consist of lists of drugs approved for use by patients' participating in that system. Formularies can be very inclusive or rather restrictive, usually termed "open" and "closed". In a closed formulary, there are certain medications that are not covered at all.

Closed formularies have been shown to increase medical costs while reducing drug costs [13], and are not used often anymore. In open formularies, which are used more frequently, the patient can receive any available therapeutic agent, but there are positive incentives either to the prescriber, pharmacist or patient for following certain guidelines in the choice of therapeutic agent. For example, Medi-Cal accepts all drugs on its contract drug list, but for some of these drugs, a TAR (treatment authorization request) code is required, and must be approved by a central office. In other Medicaid systems, a series of open formularies are used. This is an attractive option, but it may be difficult to implement in the workers' compensation sphere because one of the main enforcement methods for formularies is a series of tiered co-payments. These co-payments act to favor certain therapeutic agents (often generic agents, or agents with which the insurer/program has negotiated a discount) over other, more costly therapeutic options. It is interesting to note that the word "formulary" has fallen out of favor due to the negatives associated with the practice of closed formularies. Some systems have begun calling open formularies, prior approval lists or "contract drug lists" (indicating the need to call for approval on certain agents), and we use the terms interchangeably.

Co-pays are not allowed in workers' compensation, and therefore the effect of a formulary to lower costs may be diminished. Although co-pays cannot be used within the workers' compensation system, there may be alternate ways of "enforcing" the use of an open formulary. Increasing the amount of required paperwork, phone calls and faxes, can often have the desired "dis-incentive" factor in suggesting compliance with the formulary. If a drug is not listed on a "first tier" of therapeutics within a formulary, providers would have to climb more administrative hurdles in order to justify the use of the non-first tier drug. The added workload would encourage providers and pharmacists to enforce the formulary.

Open formularies, along with therapeutic guidelines, may prove to be an excellent option for cost control within the workers compensation system. Even without co-pays, this kind of system could involve suggestions for therapeutic treatment guidelines as the basis for formularies. These "formulary guidelines" could become part of contractual standards mandated by the Department of Workers' Compensation for contracts between insurers and PBMs or network pharmacies. With this kind of arrangement, employers in the state of California could get the advantage of cost savings with formularies, and patients get the advantages of the latest information on pharmaceutical treatment of workers' compensation-related injuries (i.e. pain management), and the state does not have to enforce the guidelines with a new governmental department, the insurers/PBMs will enforce these guidelines through their own formulary system. These guidelines could suggest a specific therapeutic or a class of therapeutics shown to be cost-effective for a particular problem, such as pain management (see Pain Management Guideline Review), and suggest that therapeutic should be listed for "first tier" use on a formulary or guideline. Therapeutic guidelines can be a method of enforcing best treatment practices for the treatment of workers' compensation patients, especially in ever-changing fields such as pain management, a component of workers' compensation pharmaceutical treatment encompassed over 90% of the drugs prescribed for workers' compensation patients[2]. For pain-patients within the workers' compensation system, it is likely that receiving the best pain management early on will result in lower overall costs to the system. More work is ongoing by our group at this moment, studying this

aspect of workers' compensation, but we can still make recommendations that the use of therapeutic guidelines within a formulary system can lower costs.

With an open formulary system, any other therapies, not on a "first tier" level, offered by the provider as therapy for a particular medical condition would have to have prior approval from the PBM or insurer. This type of system is now in force for Medicaid patients. Medicaid has an open formulary, and drugs not listed on the first tier drug list must acquire a Treatment Authorization Request "TAR" code, and a call or fax must be made to a state Medicaid office to verify approval of this alternate or brand name medication (<http://medi-cal.ca.gov>). In a study on the use of NSAID (anti-inflammatory agents which are some of the most commonly prescribed drugs in workers' compensation patients) among Medicaid patients in Tennessee, the effects of a prior-authorization open formulary were evaluated [14]. It was shown that the prior approval list system resulted in a 53% decrease in expenditure on NSAIDs over a two-year period in the early 1990s, resulting in an estimated savings of \$12.8 million for a population close to 500,000 Medicaid patients. There was no concomitant increase in Medicaid expenditures for other medical care, and there was an increase in the use of generic NSAID drugs. The prior approval system was demonstrated to be highly cost-effective, and this type of formulary system could help contain costs in workers' compensation in California.

The enforcement of the formulary, and the specific details of which agents within a drug class to use on the first tier, could still be left up to the insurer and/or PBM company, allowing the PBMs, pharmacies and insurers the flexibility to negotiate for discounts/rebates with drug manufacturers. Medi-Cal has the extensive use of rebates to the state within their drug pricing system, in return for admission into a non-restricted list of drugs, not requiring prior approval (such as a TAR code). The rebate system, where PBMs (or the state or federal government in Medicaid) negotiate with drug manufacturers for a rebate back from the manufacturer in return for guaranteeing a certain volume of sales, is a powerful method for reducing drug costs using formularies[2; 15], and should be harnessed to benefit public interest programs like workers' compensation. Formulary guidelines, part of the contractual standard set by the state, still leave room open for negotiation between drug manufacturers and PBMs regarding exactly which agent in a particular drug class will be listed as a "first tier" agent. This flexibility will allow PBMs to negotiate for lower drug prices with manufacturers, in return for a guarantee of sales volume. Often this discount is reflected in a rebate given to the PBM (and often mostly turned over to the insurer), from the drug company, after a certain volume has been reached [15]. This rebate system, and the use of PBMs should save the workers' compensation system money, and should be incorporated into formulary guidelines, and contractual standards mandated by the state, as part of AB749 and SB228.

More Supply-side Cost-containment Strategies

Other common cost-containment strategies used for medical and pharmaceutical costs throughout workers' compensation systems in the nation include: limited initial provider choice (i.e. unless previously designated, the employer may specify initial care provider), limited provider change (i.e. employee must wait 30 days to change providers), a medical fee schedule, hospital payment regulation, utilization review and bill review. Limited provider change is the most common strategy, with 80% of workers'

compensation systems using this strategy [16]. 63% of jurisdictions use a medical fee schedule, 41% limited initial provider choice, 29% utilization review, and 26% had bill review.

These cost containment strategies can be altered to fit the pharmaceutical care system within California. Limited provider change can be implemented as limited pharmacy or pharmacy network change, where the employer can specify that the employee can not change pharmacies within a certain period of time except in special circumstances. Limited initial provider choice can be implemented as a limited selection of pharmacies that have contracted with the employer or workers' compensation insurer. These two cost containment policies could be implemented in such a way as to continue to guarantee a wide array of access, while giving the employer/insurer and increased amount of bargaining power with pharmacies to negotiate reductions in drug cost or dispensing fees. Limited pharmacy choice or change policies could also guarantee pharmacies more efficient use of the administration systems they have in place to fill workers' compensation claims. As it stands, the first fill of a prescription is very difficult to obtain through the current workers' compensation system, as it often requires an approval of the claim from a claims administrator at an insurer or employer [2]. This adds delay for patient treatment and cost in administrative burden for the pharmacy. Limiting pharmacy change or choice could reduce the costs and administrative burden associated with the first fill of a prescription, as well as subsequent fills.

Drug Utilization Review

The utilization review and bill review functions can be addressed using the Drug Utilization Review (DUR) model, as has been implemented in various Medicaid systems and which is a standard PBM practice. In Nebraska, the DUR program was implemented to address the problem of inappropriate outpatient medication use, and the supplement therapy but providing education [17]. DUR involves intensive inspection of the pharmaceutical prescriptions by physicians and consumption by patients, and seeks to identify high-risk or inappropriate drug use/prescribing. The program has demonstrated results in reducing the cost of prescribed medications and reduced the risk of hospitalizations from medication related problems. In the period of April to December 1989, an average of \$180.89 per claim was saved on drug cost avoidance through the drug utilization review program. Participating care providers were shown to have made positive therapeutic changes in response to the DUR committee suggestions. California Medicaid has a drug use review committee, similar to that of Nebraska (http://files.medical.ca.gov/pubsdoco/dur/dur_home.asp).

“Public Interest” Detailing

In concert with the use of a therapeutic guideline/formulary, the use of “academic” or “public interest” detailing, either by PBMs and insurers or the state agencies might be an untapped source of cost savings by improving the standard of pharmaceutical care. In short, detailing involves educating prescribers in best practices, and pharmaceutical companies have used detailing for years as a method of education physicians as to the benefits of their products over other competitors[18-20]. Detailers,

often trained pharmacists themselves, are sent out to talk to prescribers about their prescribing practices. The public sector and workers' compensation insurers could take advantage of years of experience of drug companies' detailing knowledge, and use the same techniques to promote best pharmaceutical therapy practices for pain treatment and other workers' compensation specific problems. Prescribing problems that could be targeted include the use of drugs with low benefit/risk ratios, use of ineffective or marginal therapies for treatable conditions, use of excessive numbers of medications in vulnerable populations, use of high cost drugs in situations where lesser costs drugs would work as well, and the under-use of effective agents for major illnesses. In one documented case, there was a potential savings of 2 – 3 times greater than the costs of mounting such a program [20]. Studies have suggested that for many doctors, pharmaceutical company sponsored detailers are generally the first source of information about new therapies. State systems like workers' compensation could sponsor their own detailers, or require that PBMs or pharmacies create, "academic", "public interest" or "counter" detailing programs that work toward the continuing education of workers' compensation physicians on pharmaceutical issues and treatment protocols for the benefit of workers' compensation patients. Incorporating such practices into the repertoire of insurers and PBMs may be difficult, but might be achieved through mandated contractual standards of the Department of Workers' Compensation for Pharmacy Benefit Management companies and insurers. It is possible that such programs could be paired with a practice already in common use among PBMs, Drug Utilization Review (see more below).

Capitation and Caps

Other, more radical changes to the current fee-for-service system of pharmaceutical care have been suggested. Capitation payments to pharmacists have been tried as pilot programs under Medicaid in Iowa [21]. Capitation payment is the payment of a flat fee per patient covered (sometimes called a per member per month, PMPM). This model has been implemented throughout managed care organizations for physician and hospital reimbursement (the DRG-based prospective payment system), and many PBMs receive payment from insurers at a PMPM rate. Some PBMs have also experimented with this model for reimbursing pharmacists [15], but it is not widely in use for pharmacist payment. Within the Iowa pilot study, almost all of the pharmacists involved considered capitation a big improvement over the traditional fee-for-service system of Medicaid payment, despite concerns over accurate lists of eligible patients, difficulty making substitutions and difficulties in motivation among salaried employees. The benefit most often cited with this system was a reduction in paperwork and an improved cash flow. Workers' compensation has been cited as a system awash in paperwork, and the administrative difficulties within the WC system, and especially the difficulties acquiring approval for first prescription fill, represent significant costs within the WC system, and possibly also lead to reduced access to pharmaceutical care for workers [2]. However, there are still problems associated with the implementation of a capitation program, and given the decentralized, deregulated nature of the workers' compensation system, it may not be feasible, or advisable, in the near future.

Another suggested cost control method that has been sometimes used in Medicaid and among private insurers is the use of a prescription cap, a limit to the number of prescriptions that can be filled in a month. This may limit care for workers, whose pain management requirements often require many prescriptions in a given month, and such a policy may be met with resistance from employers and employees. Schulz et al conclude that prescription caps (i.e. 3 Rx a month) put a subset of patients at risk for underutilization complications [22], and this would likely fit our population of workers' compensation patients and so would be an undesirable method of cost control for workers' compensation.

Recommendations

Many cost containment strategies have been used to contain pharmaceutical costs, but only a few of these are easily applicable to the California workers' compensation system. They are mainly supply-side incentive programs. Some of these are already well on the way to being implemented, and others are new ideas that may require time and further study before finding their place in the California workers' compensation system.

1. **Integration and Use of PBMs**-The use of Pharmacy Benefit Management Organizations and further integration with group health and managed care organizations should be able to streamline the delivery of efficient pharmaceutical services, and take advantage of cost containment expertise and negotiating power available to these companies.
2. **Generic Mandate**- Already part of enacted legislation (AB749 and SB228), this should help reduce the costs and increase the rates of generic substitution. Further refinement to this policy may improve substitution rates further, including requiring doctors to submit extra forms to certify the need for a brand name pharmaceutical when a generic is available, the use of formularies, and a shortened prescription form that does not make the process of overwriting generic substitution easy for the prescriber.
3. **Discount to AWP for Ingredient Cost**- An extended discussion of this recommendation can be found in the Fee schedule Review section. This policy changes the current practice of paying a premium to the average whole price for ingredient cost to pharmacies to that of 100% of Medi-Cal, and would put California practice more in line with other state and government agencies.
4. **Prior Approval List/Formulary Guidelines** - An open formulary policy combined with therapeutic guidelines should be included in the contractual standards between insurers and pharmacy benefit management organizations (PBMs). This "formulary guideline" would suggest that certain therapeutic classes of drugs, shown to be more effective for the treatment of workers' compensation related injuries and pain management, to be used as first line treatment, whereas other treatment, of potentially less treatment value (and likely more expense), would be placed on a list requiring prior approval from the PBM or insurer. This policy would allow the PBM/insurer the flexibility to negotiate with drug manufacturers within that drug class for "preferred" status on a formulary, and allow workers' compensation carriers to take advantage of the

- benefits of negotiating volume discounts. This type of policy would likely be most successful when implemented by a PBM or pharmacy group.
5. **Drug Utilization Review** – Already in practice among PBMs and state agencies like Medicaid, Drug Utilization Review could be mandated within contractual standards between insurers and PBMs as a method to insure effective drug prescribing and drug use.
 6. **Public Interest Detailing** – Sending pharmacists out to talk to prescribers with “non”-optimal prescribing patterns could use the knowledge of pharmaceutical company detailers while promoting the goals of cost containment and best patient care with the latest in prescribing practice for pain management and other key fields of interest to workers’ compensation patients. This practice could be in concert with Drug Utilization Review.
 7. **Limited Provider Choice/Change** – Giving employers the power to limit which pharmacies or pharmacy chains at which an employee can receive pharmaceutical care, and/or limiting the time frame in which an employee can change pharmacies could result in cost savings and a reduced administrative load for pharmacies. This would give employers/insurers the ability to negotiate with pharmacies/pharmacy chains to reduce charges based on volume of care.

References

1. Blay, N., N. Smithline and A. Swedlow. The integration movement in California's workers' compensation market *J Ambul Care Manage* 23 (3):57-69, 2000
2. Neuhauser, F., A. Swedlow, L. Gardner and E. Edlesten. 2000. Study of the Cost of Pharmaceuticals in Workers' Compensation, Study of the Cost of Pharmaceuticals in Workers' Compensation. Commission on Health and Safety and Workers' Compensation, Oakland, CA, pp. 1-38
3. CWCI. 2002. Pharmaceutical Cost Management in California Workers' Compensation, Pharmaceutical Cost Management in California Workers' Compensation. California Workers' Compensation Institute, Oakland, CA, pp. 1-13
4. Ellis, R. P. and T. G. McGuire. Optimal payment systems for health services *J Health Econ* 9 (4):375-96, 1990
5. Reutzel, T. J. The nature and consequences of policies intended to contain costs in outpatient drug insurance programs *Clin Ther* 15 (4):752-64, 1993
6. McManus, P., D. J. Birkett, J. Dudley and A. Stevens. Impact of the Minimum Pricing Policy and introduction of brand (generic) substitution into the Pharmaceutical Benefits Scheme in Australia *Pharmacoepidemiol Drug Saf* 10 (4):295-300, 2001
7. Carroll, N. V., J. E. Fincham and F. M. Cox. The effects of differences in state drug product selection laws on pharmacists' substitution behavior *Med Care* 25 (11):1069-77, 1987
8. Anis, A. H. Substitution laws, insurance coverage, and generic drug use *Med Care* 32 (3):240-56, 1994
9. Mott, D. A. and R. R. Cline. Exploring generic drug use behavior: the role of prescribers and pharmacists in the opportunity for generic drug use and generic substitution *Med Care* 40 (8):662-74, 2002

10. Bloor, K., A. Maynard and N. Freemantle. Lessons from international experience in controlling pharmaceutical expenditure. III: Regulating industry *Bmj* 313 (7048):33-5, 1996
11. Ess, S. M., S. Schneeweiss and T. D. Szucs. European healthcare policies for controlling drug expenditure *Pharmacoeconomics* 21 (2):89-103, 2003
12. McGregor, M. Coverage of drug costs: reference-based pricing *Can J Cardiol* 14 (5):666-8, 1998
13. Kozma, C. M., C. E. Reeder and E. W. Lingle. Expanding Medicaid drug formulary coverage. Effects on utilization of related services *Med Care* 28 (10):963-77, 1990
14. Smalley, W. E., M. R. Griffin, R. L. Fought, L. Sullivan and W. A. Ray. Effect of a prior-authorization requirement on the use of nonsteroidal antiinflammatory drugs by Medicaid patients *N Engl J Med* 332 (24):1612-7, 1995
15. Lipton, H. L., D. H. Kreling, T. Collins and K. C. Hertz. Pharmacy benefit management companies: dimensions of performance *Annu Rev Public Health* 20:361-401, 1999
16. Long, A. B. and R. S. Brown, Jr. Workers' compensation introduction for physicians *Va Med Q* 122 (2):108-11, 1995
17. LeGrady, D. The Nebraska Medicaid Drug Utilization Review Program *Nebr Med J* 77 (1):3-6, 1992
18. Soumerai, S. B. and J. Avorn. Economic and policy analysis of university-based drug "detailing" *Med Care* 24 (4):313-31, 1986
19. Avorn, J. and S. B. Soumerai. Improving drug-therapy decisions through educational outreach. A randomized controlled trial of academically based "detailing" *N Engl J Med* 308 (24):1457-63, 1983
20. Soumerai, S. B. and J. Avorn. Principles of educational outreach ('academic detailing') to improve clinical decision making *Jama* 263 (4):549-56, 1990
21. Cirm, J. T. Pharmacists' views of an experience in capitation reimbursement under the Iowa Medicaid drug program *Contemp Pharm Pract* 3 (3):180-8, 1980
22. Schulz, R. M., E. W. Lingle, S. J. Chubon and M. A. Coster-Schulz. Drug use behavior under the constraints of a Medicaid prescription cap *Clin Ther* 17 (2):330-40, 1995

Patient Access to Pharmaceutical Care in Workers' Compensation in California

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Any proposal for change to the workers' compensation system in California is met with concerns that such changes will result in the reduction of access to care for injured workers. In this review, we focus on how changes to the pharmaceutical section of the Official Medical Fee Schedule for workers' compensation in California may affect access to pharmaceutical care. There are two major aspects to this problem, one being the concern that fewer pharmacies will accept workers' compensation patients if the current fee schedule is reduced, and the other concern being that other cost control measures, such as formularies, designed to reduce pharmaceutical costs may also decrease patient access.

Concern 1: Pharmacies Accepting Workers' Compensation

Commission on Health and Safety in Workers' Compensation

There is not a great deal of available literature examining the access to pharmaceutical care for workers' compensation patients in California. The most recent source of information has been the study by the Commission on Health and Safety in Workers' Compensation (CHSWC) in 2000 [1]. They examined access by analyzing a representative sample of workers' compensation pharmaceutical transactions, amounting to about 15% of the total pharmaceutical transactions for the year examined (1998-99). The study found that 60% of all the pharmacies in the state participated in at least one workers' compensation claim. In addition, there are a large number of dispensing physician's offices, hospitals and occupational medical clinics, which had data available, but which were not included in the analysis. The study then compared the location of workers' compensation patient addresses with the addresses of pharmacies offering access to workers' compensation patients, and they found that on average, there were 5 pharmacies within a 4.5 mile radius of a given worker's home address. The CHSWC study went on to say that in discussions with representatives of pharmacy chains that operate in multiple states, even those like Washington state that have a substantially lower fee schedule, they could not identify any examples of pharmacy chains that had left the workers' compensation market due to reductions in the fee schedule. This study concluded that there was little hard evidence to support claims by some stakeholders in the workers' compensation system that access was a considerable problem, and that reductions in the pharmaceutical fee schedule should not result in any significant reductions to current standards of access to pharmaceutical care. The only major problem the study sited, on an anecdotal basis, was the difficulty a worker might have in finding a pharmacy to take a claim on a lien basis if a claim was delayed or denied.

There are some weaknesses with the CHSWC review, including the fact that the pharmacies included as "serving the workers' compensation patient", were included even if they handled just one case, and may not represent frequent access conditions for the average injured worker. It has been observed in studies examining access in Medicaid,

that the number of pharmacies which have ever handled a Medicaid claim is significantly different from those pharmacies who have Medicaid cases which account for more than 5% of their filled prescriptions [2]. Still, overall the CHSWC examination of the available data suggests that access to pharmaceutical health care is currently more than adequate for workers' in California, and there is little suggestion that a reduction in the generous California fee schedule would alter that considerably.

Examining experiences with Medicaid may shed more light on the pharmaceutical access issues for workers' compensation. Most available literature on access is found relating to Medicaid programs, and many of the suggested changes to the current California pharmaceutical fee schedule are centered around using drug reimbursement rates comparable to those used by Medicaid (or the Washington State workers' compensation system, as stated in the Fee Schedule Review). Therefore, a review of access issues in Medicaid might provide important information on access expectations if fee schedules mimic those of Medicaid.

Medicaid Access: Adams et al

Adams et al have looked extensively at Medicaid access issues, and the participation of pharmacies in the Medicaid program [2]. They performed a county by county analysis of Medicaid pharmacy participation in 15 states, and they found, through intensive data analysis and modeling efforts, that the demand faced by pharmacies for Medicaid services is determined more by its location, as related to where Medicaid recipients live, than by its pricing policy on pharmaceuticals. They also concluded that Medicaid's purchasing volume and the ability of the pharmacy to price discriminate on the basis of program eligibility, made it likely that Medicaid can pay close to acquisition costs (the cost which the pharmacy pays for the drug from the wholesalers) and still maintain participation of pharmacies in the Medicaid program on the part of many pharmacies. Overall profits are greater for the pharmacy, when it offers service to a greater volume of Medicaid clientele, due to the ability to produce greater output at lower per-unit costs. In other words, the additional volume the pharmacy would handle due to having Medicaid patients would allow the pharmacy to buy ingredients (drugs) at a lower per-unit price through volume savings, therefore, allowing the pharmacy more profit for each transaction.

Their economic model came up with the following conclusions regarding pharmacy participation in Medicaid:

- If Medicaid payments fall below marginal (acquisition) costs, pharmacies are less likely to participate in Medicaid.
- Other payors, like HMO's which negotiate discounts, limit the ability of pharmacies to cost-shift to other payors
- Small pharmacies may not be able to participate in the Medicaid program, due to higher costs of doing business due to inability to negotiate high volume contracts
- Medicaid may only be able to reimburse lower rates to a threshold point (marginal cost), below this point, there is likely to be less pharmacy participation

These conclusions were based on their examination of pharmacy participation rates both by whether or not a pharmacy had ever submitted a Medicaid claim, and whether or not Medicaid claims accounted for more than 5% of the total prescriptions dispensed at that pharmacy. The rates of participation in Medicaid differed between chain and independent pharmacies, both in the “at least one” category, as well as the “>5%” category. Chain pharmacies, had an overall 93% participation in the “at least one” category, with rates varying between 93% in higher-income areas, and 98% in high poverty areas. Independents, on the other hand, had a lower rate of participation at the “at least one” level, with 82% of such pharmacies participating in Medicaid, at 82% in high-income area, and 80% participation in high-poverty areas. This is important, because many of the pharmacies which locate in high-poverty areas are independents, and it is interesting that some of them do not accept Medicaid. However, for the pharmacies where more than 5% of prescription filled had Medicaid claims, the independent and chain pharmacies became more equitable overall, with 67% participation at this level for chains, and 68% participation for independents. But, chains have a much higher level of “>5%” participation in Medicaid in high poverty areas, with a participation rate of 95%, versus independent pharmacies, which have a 75% participation at that level. That specified “>5%” value for Medicaid prescription out of total prescriptions actually represents about 10% of total prescriptions for chains, and 15% for independents. So, even though independents are more likely to locate in high poverty areas, and be more dependent on Medicaid cases for volume, they have a lower participation rate in Medicaid than the independents, especially in high poverty areas. If we assumed that these results can be applied directly to the workers’ compensation environment, this would mean that independent pharmacies overall, and especially in high poverty areas, would be less likely to accept workers’ compensation patients than would chains, if the reimbursement rate for workers’ compensation was lowered to a rate closer to that of Medicaid. Still, the Medicaid participation rates for even the high poverty areas still topped 75%, and that would still mean a high level of access for workers’ compensation patients.

Differences between Workers’ Compensation and Medicaid

There are important differences between the Medicaid and workers’ compensation systems; some of which will make it more likely that workers’ compensation patients will find equal or greater access than Medicaid patients, and a few that might offer a disincentive for access. For example, the Adams et al model indicated that pharmacies are less likely to participate in Medicaid in states where they must try to collect a copayment. This is good news for the workers’ compensation patient, who does not require a copayment or coinsurance of any kind, and speaks well for access in pharmacies which already serve Medicaid patients. There are differences in scale between the Medicaid system in California, and the workers’ compensation system, and we can use some rough estimates to compare the size of these two programs. The CHSWC reports that 600,000 transactions in the CWCI database they examined account for 20% of workers’ compensation pharmacy transactions. This would mean that in a given year, there are 3,000,000 pharmacy transactions involving workers compensations.

For Medicaid (Medi-Cal in California), it is estimated that there is an average of 10.4 prescriptions filled per patient per year [2]. With between 5.5 and 6.5 million people currently on Medi-Cal (<http://www.work-and-health.org/Reports/WorkGroupReport.html>), that means that there are approximately 55,000,000 to 65,000,000 pharmacy transactions involving Medi-Cal patients, an order of magnitude greater than that of workers' compensation transactions. Given this difference in scale, a less generous fee schedule for workers' compensation should have a relatively small impact on pharmacies, and would be less likely to affect access to care, but the low volume of workers' compensation patients in comparison to Medicaid patients may lead to decreases in access over time.

There are also differences in the type of treatment being sought with Medi-Cal patients vs workers' compensation patients. Medicaid patients are a mixed group, ranging from children to the blind and disabled to the poor elderly, with different pharmaceutical requirements than workers' compensation patients. The workers' compensation population is most often younger, and seeking pharmaceutical treatment for pain or pain-related conditions. Also, workers' compensation patients come from a broader array of socio-economic backgrounds, with an average income higher than that of Medicaid patients.

Unfortunately, current accessibility to pharmaceutical care for workers' compensation patients may be due, in part, to a very generous fee schedule. Planned reductions to this fee schedule, such as the replacement of the OMFS fee schedule with the current Medi-Cal fee schedule, might result in reductions to access. However, the Medi-Cal fee schedule is still more generous than the pharmaceutical reimbursement offered by managed care organizations (often 15-20% less than AWP)[1], and so more desirable to pharmacies.

Lowering the workers' compensation fee schedule to Medicaid levels would have some disincentives for access, including 1) difficulties with workers' compensation eligibility requirements for determining the eligibility for a first fill of a prescription on a new claim, 2) workers' compensation will not have the volume advantages that Medicaid can provide and 3) increased administrative costs associated with antiquated processing and adjudication services with some workers' compensation insurers and self-insured employers. Some of the above disincentives are currently problems with the workers' compensation system, and would only cause more problems when the reimbursement fee schedule is lowered. Problems determining eligibility of new claims, from the length of time to confirm eligibility to the load of administrative paperwork, is a major concern for pharmacies participating in workers' compensation, and will continue to be so with a reduction in the fee schedule [1]. To counterbalance these disincentives, or to have enough available time to deal with these problems, one approach might be to gradually lower the fee schedule to Medicaid rates over a two year time scale. Still, these disincentives will have to be addressed as cost control measures, in order for access to pharmaceutical care to be maintained or increased for workers' compensation patients.

Concern 2: Cost Control Measures

Another aspect to access to pharmaceutical care is the ability of the patient to obtain the needed pharmaceuticals, given that a pharmacy allows them coverage. Some

cost containment measures run the risk of decreasing access to patients. In Medicaid, reductions in access have been noted in states that enforce copayments, no matter how modest, and reductions in access are especially apparent in states with a prescription cap, typically 3 or 4 prescriptions a month [3]. The results of these access problems were shown to suggest a decrease in the overall health of patients, and an increase in other medical services, such as hospital admissions [4]. These two kinds of cost containment policies are not likely in the context of workers' compensation, where medication caps or copayments are not used, but it is still important to examine the impact of other cost containment policies that might be considered by workers' compensation administration, and how they may affect access to pharmaceutical care.

Transaction Costs/First Fill Policies

Some proposed cost control measures may result in reduced access for workers' compensation patients to pharmaceutical care, but some cost control measures may result in increasing access to care. Updating pharmacy transaction systems could be a cost control measure that results in increased access. Pharmacies handling workers' compensation patients have to deal with an additional load of administrative procedures, relating to the determination of eligibility. Pharmacies cite administrative problems as burdens to care, and patients cite administrative problems with achieving access [1]. Transaction simplification and streamlining has been an important part of some of the most effective workers' compensation systems, and is a top priority for cost control [1]. The Washington State workers' compensation system, which has the lowest reimbursement rate in the country for workers' compensation pharmacy benefits (normally AWP-10%, almost equivalent to Medicaid without Federal Upper Limit pricing), did not implement their system without streamlining administration and transactions. The Washington system fee schedule only went into effect after intensive negotiations to improve the transaction process between pharmacies and payers (in this case the Washington Self-Insurers Association, the WSIA) [1]. They implemented a point of sale (POS) automatic adjudication system [1].

Updating transaction systems, while incurring an initial capital expenditure, results in faster, more efficient payment to pharmacies; fewer denials of eligible claims; less administrative paperwork load both for pharmacies and insurers. The incentive in Washington to pharmacies to update their transaction procedures included guaranteed payment for new claims that had not been processed or accepted. This kind of "first fill" guarantee would be a powerful incentive to pharmacies to maintain or increase access to workers' compensation employees, regardless of the fee schedule reimbursement amount, because of the savings in administrative costs. A first fill guarantee has the potential to promote increased access by simplifying administrative procedures for pharmacies. Limited first fill guarantees, which would pay for the first prescription on a claim, whether or not the claim was later approved, would significantly lessen the administrative burden on pharmacies. Since less than 2% on claims are denied under these circumstances, this would not represent a significant cost to the insurer and employer, versus the savings in transaction and administrative fees [1]. Both insurers and pharmacies may need to be given incentives to update their transaction systems for pharmacy payment.

Pharmaceutical Benefit Management Organizations

The introduction of Pharmaceutical Benefit Management Organizations (PBMs) into the workers' compensation field will speed the process of updating transaction systems, as they have more advanced, often electronic, systems already in use, and can make administration more efficient [5]. PBMs are organizations that act as negotiators between pharmacies, insurers and drug companies. They process transactions, maintain formulary lists, and negotiate rebates from drug manufacturers based on volume of sales. As such, the use of PBMs as a cost control measure may also result in increased patient access. POS systems are customary in the group health sector, and they are made up of electronic interfaces between the payor and the pharmacy that automatically identify the eligibility of a customer, and the price of reimbursement for that prescription. PBMs can help to update the outdated workers' compensation transactions by using their own systems, already in place for dealing with group health insurers, and PBMs already use POS systems and "first fill" guarantees to lower the cost of transactions. There have been some suggestions that the use of PBMs by insurers and employers would limit the amount of pharmaceutical access for employees, but experience in other state systems has shown that to be a minor concern [6]. In Georgia, their recruitment profile for PBMs to take over the pharmaceutical benefit management for Medicaid had the requirement that patient access would be guaranteed to be feasible in 95% of pharmacies in the state [6] (in other words, a Medicaid patient could walk into 95 out of 100 pharmacies and receive service from the PBM contracted). Within Georgia, the overall pharmacy network coverage rate was 98%, and most of the specific PBM companies answering the recruitment effort already had the required 95% coverage. Given that the current rate of participation in workers' compensation in California for pharmacies is at about 60% of pharmacies [1], the use of PBMs in the state might actually significantly increase access, if the level of coverage in California is anywhere close to that of Georgia.

Reutzel et al discuss a list of "problem-solution" principles that can be applied to reimbursement policies for pharmacies [7] They state that any payment formula should 1) cover the pharmacy's true economic costs; 2) not encourage higher administrative costs; 3) not subsidize others (eg purchasers of front end merchandise); 4) be based on uniform cost accounting information; 5) be flexible; 6) encourage the provision of services that benefit the patient; and 7) require prompt payment. Cost containment policies and fee schedules relating to workers' compensation should attempt to follow these parameters, and if successful, access should be maintained or increased, as pharmacists are satisfied with the payment system. Not enacting a sudden, drastic change to the fee schedule, overhauling the transaction system, guaranteed first fill programs, and the engagement of experienced PBMs in the workers' compensation marketplace should maintain or increase access for most workers' compensation patients to pharmaceutical care.

Prior Approval Systems: Reducing Costs at the Risk of Reducing Access?

There are several types of prior approval systems that are used to decrease the costs of drugs. They are formularies, but often other names are used, such as "prior

approval list”, “positive list”, “negative list”, “contract drug list” or in Medi-Cal the TAR (treatment authorization request) system. It is important to differentiate here between “closed” and “open” formularies. ”. In a closed formulary, there are certain medications that are not covered at all. Closed formularies have been shown to increase medical costs while reducing drug costs [4; 8], and are not used often anymore. In open formularies, which are used more frequently, the patient can receive any available therapeutic agent, but there are positive incentives either to the prescriber, pharmacist or patient for following certain guidelines in the choice of therapeutic agent. Open formularies can also be called preferred drug lists, brand name drug restrictions, or therapeutic consultation services [9]. In the Medicaid system, the Omnibus Budget Reconciliation Act of 1990 disallowed restrictive, closed formularies, and as a result, access to medications in the Medicaid population increased [8]. There are several studies available examining the effects of closed formularies [4; 8; 10], but few that concentrate on open formularies. Most current studies discuss the rate at which administrative barriers such as increased paperwork, or extra phone calls result in reductions in access. Open formularies do not have the extent of access problems that closed formularies do [8], but that does not completely eliminate any potential for reduction in access.

Linda Gorman, of the Health Care Policy Center Independence Institute, cites that open formularies do still have many restrictions on access to drugs, and that prior approval programs result in added difficulties in achieving access for the most “at-risk” or fragile patients [9]. She cites problems with the Florida Medicaid program, where patients had difficulty obtaining access to brand name pharmaceuticals, and so had increased rates of negative outcomes. A common problem cited was the inability to get “early” refills of important prescriptions before a new prior authorization could be processed, resulting in a period of time when the patient went without medication while waiting for paperwork to be processed through the system. In the workers’ compensation system, this could result in patients being in pain, or having to travel to get prescriptions filled. It is important to plan for these types of situations in the creation of a prior approval policy for California workers’ compensation, and make sure that a prior approval policy created for cost savings does not interfere with timely and thorough patient care.

Medi-Cal uses a prior approval system referred to as the TAR (Treatment Authorization Request) system. This system has a “contract drug list” that lists all drugs, and designates which drugs require a prior approval or TAR form in order to have the prescription filled. These TAR requests are cleared through special Medi-Cal offices. Drugs that don’t require a TAR form are often drugs that have had discounts or rebates negotiated on the federal or state level. Due to these negotiated discounts, it is doubtful that workers’ compensation would be able to exactly copy the Medi-Cal prior approval process, but contract standards developed for AB749 fulfillment could include a mandate for insurers to develop their own prior approval/formulary lists.

In the Cost Containment Review, we advocate the use by workers’ compensation insurers/self-insured employers, of an open formulary or prior approval system, which could help to implement therapeutic guidelines for pain management or other diagnoses for injured workers, as well as a method of controlling inappropriate use of high cost pharmaceuticals, by requiring an oversight or approval before dispensing. There may be some concern that this process, requiring some additional administrative burden both for

the pharmacist and the physician, will result in more difficulties for the patient to receiving needed care. However, if the guidelines/formulary reflects the best pharmaceutical practice, the patient should be getting more appropriate care more efficiently. It may be necessary to have pharmacist input in creating and maintaining these guidelines/formulary standards.

The ultimate goals of such a prior approval system are twofold: 1) to allow the PBM/insurer the ability to have a “preferred agent” list that allows high volume discounts or rebates to be negotiated with drug manufacturers, 2) to advocate state of the art treatment for pain management in the workers’ compensation population (pain or pain related drugs account for over 90% of prescriptions in the workers’ compensation system [1; 5]), and to reduce the prescribing of unnecessary or marginal therapies.

Although the enactment of open formularies within workers’ compensation may reduce access to specific high cost drugs by making it slightly more difficult to procure certain medications, overall, any drug would be available if the physician insists. A counterbalance to this effect is the inclusion of PBMs into workers’ compensation administration, as discussed above. PBMs, with their economies of scale and extensive previous experience with the implementation of formulary policies, should be able to make the implementation of a workers’ compensation prior approval list or open formulary as smooth and hassle free as possible for the patient, the physician and the pharmacist.

Conclusions

The current patterns of access to pharmaceutical care for workers’ compensation patients should not change significantly with a reduction in the Official Medical Fee Schedule for pharmaceuticals, whether the Medicaid or Washington State reimbursement system is used [1; 2]. Barriers to access can be lessened through incentives to encourage updating the transaction system for reimbursement and eligibility determination through a Point of Sale system, such as that used in Washington State. Access to pharmaceuticals in workers’ compensation should be improved by the inclusion of Pharmaceutical Benefit Management Organization and pharmacy networks. All of the desired policies, including “first fill” policies, electronic transaction processing, and streamlined open formulary implementation can be best accomplished with pharmacist involvement. Although a given employee may be required to go to a particular pharmacy in his or her neighborhood in order to find a participating provider, many pharmacy networks have a high degree of coverage, and this level of coverage statewide can be mandated within contractual standards, as was done for the recruitment of a PBM for the Georgia Medicaid program [6]. The implementation of open formularies and prior authorization codes may make access to certain pharmaceuticals slightly more difficult, but should not affect overall access to care. Access can be maintained or improved with these policies, regardless of the implementation of a reduced fee schedule for workers’ compensation.

References

1. Neuhauser, F., A. Swedlow, L. Gardner and E. Edlesten. 2000. Study of the Cost of Pharmaceuticals in Workers' Compensation, Study of the Cost of Pharmaceuticals in Workers' Compensation. Commission on Health and Safety and Workers' Compensation, Oakland, CA, pp. 1-38
2. Adams, E. K. and N. Gavin. Patterns of pharmacy participation in Medicaid: implications for enrollee access *Inquiry* 33 (4):339-51, 1996
3. Cunningham, P. J. Prescription drug access: not just a Medicare problem *Issue Brief Cent Stud Health Syst Change* (51):1-4, 2002
4. Kozma, C. M., C. E. Reeder and E. W. Lingle. Expanding Medicaid drug formulary coverage. Effects on utilization of related services *Med Care* 28 (10):963-77, 1990
5. CWCI. 2002. Pharmaceutical Cost Management in California Workers' Compensation, Pharmaceutical Cost Management in California Workers' Compensation. California Workers' Compensation Institute, Oakland, CA, pp. 1-13
6. Bae, J. P. and P. G. Justice. Pharmacy benefit management contracting: an assessment from a recent public sector procurement experience *J Health Care Finance* 29 (1):49-56, 2002
7. Reutzell, T. J. The nature and consequences of policies intended to contain costs in outpatient drug insurance programs *Clin Ther* 15 (4):752-64, 1993
8. Walser, B. L., D. Ross-Degnan and S. B. Soumerai. Do open formularies increase access to clinically useful drugs? *Health Aff (Millwood)* 15 (3):95-109, 1996
9. Gorman, L. 2002. Medicaid Drug Formularies, Medicaid Drug Formularies. Independence Institute, Health Care Policy Center, Colorado, pp. 1-22
10. Soumerai, S. B. and D. Ross-Degnan. Experience of state drug benefit programs *Health Aff (Millwood)* 9 (3):36-54, 1990

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Pharmacoeconomics:

“Pain Management Protocol”

July 31, 2003

Introduction

The growing cost of prescription drugs benefit for injured worker is increasing rapidly. In 1996, the cost of pharmaceuticals in California Workers' Compensation is approximately 114 million which translate into 3.8% of total workers' compensation medical costs. The projected estimation with an annual 12% growth rate for pharmaceutical and 7% for overall WC medical cost indicated that by year 2005, prescription coverage will assume 7.3% of total medical costs and require 374 million dollars to maintain. The cost of drugs prescribed in WC is increasing and it is important to design a treatment protocol to provide clinicians a valuable tool to combat the ever-increasing health care cost.¹ California Workers' Compensation provides complete medical coverage for injured workers. Over 90% of the prescriptions are written for the treatment of muscular skeletal pain.¹ With this in mind, controlling the cost of pharmaceuticals in WC needs to focus on pain medication and management.

Pain Assessment

Assessment of pain management includes evaluation of the pain intensity, pain characteristic/quality and pain duration (i.e. acute, chronic or breakthrough pain).² Intensity of pain should be assessed prior to initiating appropriate treatment and reassessed continuously throughout the duration of therapy. Frequent evaluation of the pain intensity is useful in determining if the patient is receiving adequate pain relief with minimal side effects. Well-controlled pain can ensure patient compliance with other concomitant medications and facilitate his or her return to work. There are several pain intensity scales, which can be selected from, based on patient's preference and cognitive ability. A few examples are The Verbal Descriptor Scale, The Numeric Rating Scale and The Visual Analog Scale.² The verbal descriptor scale is useful in patients who can describe the level of pain verbally. The numeric rating scale allows the patient to check the number that best represents their level of pain with 0 being no pain and 10 being the worst pain. The visual analog scale rates the pain intensity on a 10cm line with no pain and extreme pain marked on each side of the scale. It is beneficial for patients who cannot use numbers or words to express their pain; however, scoring is time consuming.

The quality of pain can help determine the mechanism of pain, the site of tissue injury and the most appropriate treatment regimen.² The three categories of pain diagnosis are nociceptive pain (somatic or visceral), neuropathic pain, and mixed pain (*figure 1*). Nociceptive pain is caused by damage to the tissue and it is the most frequent type of pain experienced by injured workers. It is further subdivided into somatic and visceral pain. Somatic pain is caused by activation of pain receptors in either cutaneous or muscular skeletal tissues.³ It often arises from bone, joint, muscle, skin or connective tissues. Somatic pain is characterized by well-localized, constant, dull, and aching pain increased by movement (i.e. osteoarthritis). Visceral pain arises from visceral organs that lead to poorly localize referred pain. It is characterized by deep, aching, cramping and pressure-like pain (i.e. myocardial infarction). Neuropathic pain is caused by injury to the nervous system lead to abnormal processing of sensory input. This type of pain is

described as burning, shooting, tingling, electroshock-like pain (i.e. carpal tunnel syndrome). Some patient might experience mixed nociceptive and neuropathic pain.

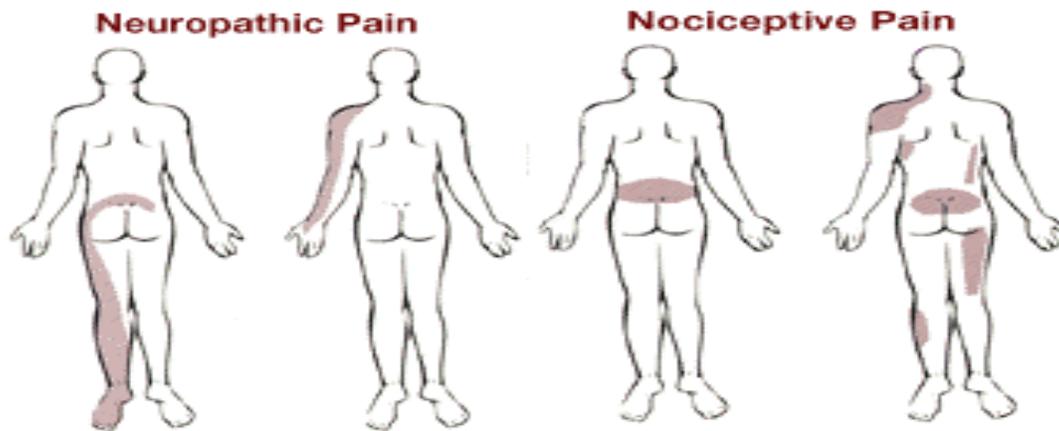


Figure 1. Adopted from www.back.com

The temporal aspects of the pain can influence a patient's quality of life and ability to return to work. It is important for the clinician to explore whether the pain is an acute, chronic or breakthrough event. Acute pain represents a body's reaction to the extent of injury. Chronic pain can occur after the initial acute pain and when the pains persist beyond expected healing time and often has no identifiable etiology. It is typically defined as pain lasting for longer than 2 to 4 months after the initial injury.⁴ Chronic pain often lasts for a long period of time and is not relieved by standard pain management therapy. The breakthrough pains are severe intermittent pains that occur while the pain is properly managed. It can occur spontaneously or right before the next scheduled dose of medication (end-of-dose pain).

Treatment Protocol

After assessment of the baseline pain intensity and characteristic, patient's pain regimen can be selected base on a step-wise ladder approach proposed by World Health Organization (*figure 2*). In 1990, WHO proposed a three step analgesic ladder that served as a guideline to treating patients with mild to severe pain intensity. The guideline was later validated in a ten-year prospective study and shown to have satisfactory or better pain relief in 90% of treated subjects.⁵ The proposed pain management protocol suggested using non-opioids such as aspirin, acetaminophen, or Nonsteroidal Anti-inflammatories to manage mild pain. As the pain persists or worsens, low potency opioids such as codeine or hydrocodone in combination with non-opioids should be recommended. Tramadol is an alternative to opioid with minimal abuse potential and is FDA approved to treat mild to moderate pain. As the pain progresses to severe pain, potent opioids such as morphine, oxycodone, or hydromorphone should be prescribed. An opioid is an effective medication for acute and chronic nociceptive pain; however, prolonged periods of treatment could lead to tolerance, addiction and side effects.² Adding adjunctive medication such as gabapentin or tri-cyclic antidepressants can enhance the efficacy of the opioid and lessen the analgesic dose of the opioids, hence decreasing the dose dependent side effects, such as sedation and respiratory depression, of the opioids. Tri-cyclic antidepressants also have the added benefit of treating

depression. Other anti-epileptic medications, such as carbamazepine, also could potentate the analgesic effects of opioids, but they are more toxic and required frequent laboratory monitoring. Other non-pharmacological therapies including heat, cold, massage, muscle relaxation techniques, education, acuapunctures and exercise could diminish pain and reduce the frequency of injuries. The step-wise ladder approach is discussed in more detail below.

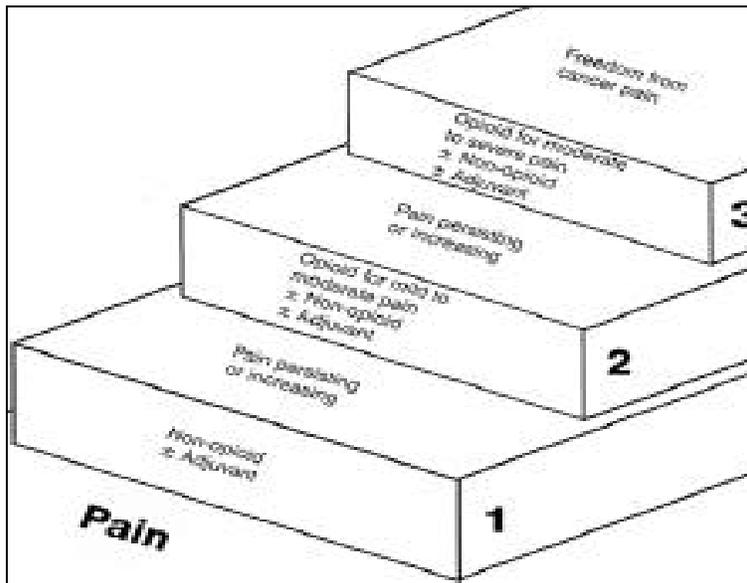


Figure 2. WHO Analgesic Ladder

Step 1: Mild Pain

NSAIDs including aspirin are effective anti-inflammatory, antipyretic and analgesic agents. The common concern with prolonged nonselective NSAID (i.e. ibuprofen, naproxen) use is gastrointestinal side effects such as dyspepsia and gastric ulcer. Patients receiving NSAIDs on a regular basis are twice as likely to have upper GI problems, and approximately 15-30% of NSAID treated patients develop gastroduodenal ulcer.⁶ The COX-2 selective inhibitors (i.e. celecoxib, rofecoxib) have minimal effects on gastric and renal protective prostaglandines that are produced by COX-1 enzymes, and hence might reduce GI irritation, sodium and water retention, and anti-platelet activity. Therefore COX-2 selective inhibitors offer similar anti-inflammatory and analgesic effects as conventional NSAIDs with improved GI safety profile.⁷ COX-2 selective inhibitors are more expensive, but they might be beneficial for patients who are taking NSAIDs for chronic pain, especially for patients who are hypersensitive to NSAIDs or with relative contraindications such as a history of peptic ulcer disease, GI bleeding, coagulopathy, hepatic disease or renal insufficiency. Acetaminophen also could be prescribed as an effective alternative for treating mild pain. Acetaminophen should be limited to 4 gram per day in healthy adults and 2 gram per day in individuals with liver disease or history of alcohol abuse.

Step 2: Moderate Pain

If pain is not adequately managed by NSAIDs or acetaminophen or the patient is suffering moderate to severe pain intensity, an opioid should be added to the NSAIDs or acetaminophen. Codeine, hydrocodone, low dose oxycodone or tramadol is used to

manage moderate pain in combination with non-opioids. A few examples of combination treatments are hydrocodone with acetaminophen (Vicodin), and codeine with acetaminophen (Tyco #2,3,4). It is important to be aware that both codeine and hydrocodone are hepatically metabolized by Cytochrom P-450 2D6 isoenzyme into more potent analgesic metabolites. Codeine is rapidly converted into morphine for its analgesic effect. Patients concurrently taking potent CYP2D6 inhibitors, such as quinidine, fluoxetine, and cimetidine) will experience a decreased formation of the active metabolite, morphine, and decreased pain relief.⁸ Hydrocodone is also metabolized into a potent opioid, hydromorphone but the effect of inhibiting CYP2D6 metabolism is less pronounced. Some studies show that there is no significant difference in pain threshold of the patients who are concurrently receiving potent CYP2D6 inhibitors with hydrocodone.⁹ Awareness of these findings can help clinicians avoid treatment failures due to drug/drug interactions. An alternative for patients who cannot tolerate the side effects of opioids or with a history of substance abuse or poor response to opioids in the past, can use tramadol as an effective alternative. Tramadol is nonopioid that binds to mu opiate receptor.¹⁰ Tramadol is effective, well tolerated and highly unlikely to lead to dependence. Tramadol was also found to have lower incidence of constipation compared to opioids and no risk of respiratory depression.^{11,12} Major side effects of tramadol are dizziness and sedation so extra precaution is required to prevent falls in the elderly. It is also associated with a risk of seizures, and hence to be used with caution in patients with seizure disorders.¹³ Concomitant use of tramadol with Selective Serotonin Reuptake Inhibitors (SSRI) might increase the risk of seizure as well.¹⁴

Step 3: Severe Pain

For patients who did not respond well to the above therapeutic management or who are experiencing severe pain, potent opioid analgesic might be indicated. There are several questions that need to be addressed before implementing opioid therapy: 1) Are there reasonable alternatives available to control pain? 2) Is the patient's pain and functional status likely to improve with opioids? 3) Is the patient likely to abuse opioids?⁴ If a formal trial of opioid is indicated, it is important to educate the patient to take the opioid around the clock instead of on an as-needed basis. Opioid dose however should be adjusted based on pain intensity and tolerability. There are several different formulations of potent opioids. Sustained release preparations of morphine (MS-Contin), oxycodone (Oxy-Contin) or transdermal fentanyl patch are used to provide baseline pain control. Immediate release preparations of morphine, oxycodone and hydromorphone are used on an as needed basis to treat breakthrough pain. It is often necessary to switch from one opioid to another due to intolerance to the side effects or need to change route of administration. Clinicians need to know the opioid equianalgesic dose between different opioids in order to prevent acute exacerbations or overdoses (*figure 3*).¹⁵ Cross-tolerance between different opioid analgesic exists but are incomplete, therefore doses are reduced by one-third when interchanging between opioids to prevent acute toxicities such as sedation and respiratory depression.

It is expected that constipation will occur while taking opioids. Patients should be treated prophylactically with stimulant laxatives, such as senna or bisacodyl, in addition to stool softeners around the clock. Common side effects such as sedation, nausea and

vomiting are transient. If the sedation persists and is intolerable, it can be managed with the CNS stimulants, dextroamphetamine.¹⁷ Respiratory depression is a major concern with opioid therapy. It seldom occurs at therapeutic doses but the risk is substantially increased in combination with other CNS depressants such as benzodiazepine, alcohol, cocaine and barbiturates. Respiratory depression may be reversed with an opioid antagonist, naloxone; however, patients might experience rebound pain. Other cognitive impairments such as slow mentation, or hallucinations, should also be monitored closely, especially in the elderly population with a risk of falling. Switching to another opioid analgesic may reduce the cognitive changes. The use of meperidine is not recommended for initial or chronic pain management because repetitive dosing leads to accumulation of the toxic metabolite, normeperidine, which can cause seizures.¹⁶ Precautions should also be placed on patients receiving methadone for chronic pain management. Methadone is inexpensive and has a long plasma half-life, but repetitive dosing could lead to drug accumulation and sedation, confusion, and even deaths have been reported.

Figure 3: Equianalgesic Dosing Conversion

Opioid Analgesic	Equianalgesic Dose	
	Oral	Parenteral
Morphine (Roxanol, MScontine)	30	10
Hydromorphone (Dilaudid)	7.5	1.5
Oxycodone (Percocet, OxyContine)	20	--
Methadone*	20 (acute) 2-4 (chronic)	10 (acute) 2-4 (chronic)
Hydrocodone (Vicodin, Lortab, Norco)	30	--
Codeine (tyco #2=15mg, #3=30mg, #4=60mg)	180-200	130
Fentanyl Transdermal (Duragesic)	2:1 rule**	--

Adopted from UCSF Adult Pain Management Guideline

* Titrate slowly because long half-life and dose accumulation toxicity.

** If the total 24 hours dose of oral morphine is 100mg, the approximate equianalgesic dose of transdermal fentanyl is 50mcg/hr or 2:1 equivalency.

Documentation is important, especially in treating patient with opioid analgesics, because of the additive potential and the harmful side effects of the medication. Attached is a copy of Opioid Progress Report Supplement provided by State of Washington Department of Labor and Industry, which includes a treatment agreement, an opioid progress report supplement, and a functional progress form. Due to the intricacy of pain management, patients should be advised to visit the clinic at least every two weeks for the first two to four months, then at least once every six to eight weeks while receiving opioids. The Opioid Progress report and the Functional Progress form should be completed at every visit. Clinicians should reevaluate the need to continue opioids every

two months and consider discontinuing the opioids if there is a 1) lack of overall improvement in pain and functional status or 2) complete resolution from the injury.⁴

Acute and Chronic Low Back Pain

Back injury is the most common causes of all disabling injuries in the recent Worker's Compensation Census. It accounts for 23.7% of all work-related injury and 19.7% incurred medical expenses in total worker compensation benefits.¹⁸ The most common site for pain is the lower back because it bears the most weight and stress. Many causes may contribute to low back pain, including obesity (which increases the weight on the spine and the pressure on the discs) and repetitive stresses on the muscles and ligaments which support the spine due to improper or heavy lifting. Major signs of back pain are 1) muscle strains due to inflammation of the back muscles, tendon or ligament; 2) muscle spasms in response to back injury; 3) sciatica caused by compression of the sciatic nerve at the base of the spine may be due to poor posture or muscle strain and leads to radiating pain in the leg; and 4) Herniated disc when the disc around the spine becomes damaged from an injury, normal wear and tear, or disease.¹⁹ The pain occurs when the herniated disc breaks off or bulging fragments begin to compress the nerve. The majority of injury related low back pain is caused by muscle strains and spasms. They usually are a mild pain lasting for four to six weeks that can be treated with heat, cold and massage. Non-steroidal anti-inflammatory drugs or acetaminophen may provide sufficient relief for the mild back pain. Severe back pain due to sciatica or herniated disc might require opioids and adjunctive treatments to suppress the pain. Since herniated disc and sciatica are generally neuropathic pain, adjunctive treatments such as gabapentin or tricyclic antidepressants might provide added pain relief if opioid monotherapy fails. The recurrence of back pain is high. It is important to exercise regularly and follow proper body mechanics when lifting heavy objects to avoid these injuries.

Neuropathic Pain

Neuropathic pain occurs when there is actual nerve damage in the central or peripheral nerve system. It may be caused by compression on the nerve lead to radiating, burning, tingling or lancination pain.² Carpal Tunnel Syndrome occurs when tendons or ligaments in the wrist became inflamed and swollen due to repetitive trauma on the wrist which leads to compression of the median nerve. Neuropathic pain is a chronic pain often requiring surgical intervention to alleviate the nerve compression. It also does not respond well to standard analgesic therapy. Some studies suggested that tri-cyclic antidepressants and anticonvulsants are more effective than opioids and NSAIDs in this type of pain. Tri-cyclic antidepressants potentate the analgesic effect of opioids as well as being effective against neuropathic pain; however, they are associated with anticholinergic side effects such as dry mucus membranes, sedation, dizziness, somnolence, orthostasis, and potential risk of mortality if overdosed.²⁰ Carbamazepine is the first anticonvulsant to demonstrate efficacy in the treatment of neuropathic pain; however, long-term side effects included blood dyscrasia, severe hypersensitivity reaction, arrhythmia, and possible death. Frequent blood tests for Complete Blood Count

with differential is required which adds to the expense of treatment. Gabapentin is also an anticonvulsant with FDA indication for postherpetic neuralgia. It is effective against neuropathic pain with minimal side effects and routine laboratory monitoring is not necessary. Efficacy was demonstrated over a range of dose from 1800 mg per day to 3000 mg per day.²¹

Cost Saving Analysis: Morphine SR vs Other Treatments

The usual starting dose for MS-Contin control release tablets to treat severe pain is 30 mg every 8 to 12 hours. The cost of MS-Contin per day is \$4 to \$6 at approximately \$2 per tablet. The equianalgesic dose of Oxy-Contin is 20 mg to 40 mg every 12 hours. The cost of Oxy-Contin per day is between \$6 to \$9 at approximately \$3 per tablet. The cost of initiating or maintaining pain management on 30 mg every 8 to 12 hours with generic morphine sulfate sustained release formulation is \$3.4 to \$5 per day at approximately \$1.7 per tablet. The insurer will save approximately \$20 to \$30 per patient per months if the patient was initiated or maintained on generic instead of brand name morphine sulfate sustained release. The insurer will save approximately \$80 to \$120 per patient per day if the patient was initiated or maintained on generic morphine sulfate sustained-release instead of Oxy-Contin. The immediate-release oxycodone and hydromorphone are relatively cheaper on a per tablet basis compared to sustained-release formulation; however, the risk of breakthrough pain and the inconvenient dosing schedule neglect the cost saving (*figure 4*). It is beneficial for the clinicians to initiate sustained-release formulations to achieve constant pain relief.

Figure 4. Cost Saving Analysis

Name	Initial Dose (mg)	Dose Interval (hr)	Cost per day	Cost Saving/ month/patient
Morphine SR	30	8 – 12	\$3.4 - \$5	\$0.0 (baseline)
MS-Contin	30	8 – 12	\$4 - \$6	\$20 - \$30
Oxy-Contin	20	12	\$6	\$80
Fentanyl Patch	25ug/hr	48 – 72	\$30 per patch	\$150 - \$200
Hydromorphone	4	4 – 6	\$3.0 (Brand) \$2.0 (Generic)	---
Oxycodone	5	4 – 6	\$1.5 - \$2	---

In Conclusion

The goal of the pain management protocol is to provide the clinician a step-wise approach to controlling pain as well as to provide cost effective care. Managing pain using ladder approach is one way of ensuring cost effective care. For example, it is preferable to manage mild pain with NSAIDs instead of an opioid. For moderate pain, it is more effective and efficient to initiate a weak opioid such as hydrocodone or codeine to relieve the pain. Vicodin or hydrocodone and Tylenol with codeine are also available in cheaper generic formulations that provide similar efficacy as the brand name but cost less. Potent opioids, such as morphine, hydromorphone and oxycodone, should be reserved for severe and uncontrollable pain. Based on the cost saving analysis, it is

preferable on a cost basis to prescribe generic morphine sulfate sustained release to provide baseline pain suppression and nonopioids such as acetaminophen or NSAIDs for breakthrough pain. The opioid equianalgesic chart allows interchange between potent opioids and maintains effective pain management. The cost of pharmaceuticals in Worker's Compensation is increasing rapidly. It is up to the prescriber, insurer and the injured workers to curtail the increasing pharmaceutical burden while maintaining optimal care outcomes.

References

1. Neuhauser F, Swedlow A, etc (2000). Study of the Cost of Pharmaceuticals in Workers' Compensation. Commission on Health and Safety and Workers' Compensation: 1-36
2. Abrahm JL, Snyder L. Pain Assessment and Management. Primary Care. 2001 June;28(2):269-97
3. Institute for Clinical Systems Improvement (ICSI). Health care guideline: Assessment and Management of Acute Pain. Oct 2002
4. State of Washington Department of Labor & Industries. Provider Bulletin: Payment for opioids to treat Chronic Noncancer Pain. May 2000: 1-23
5. Zech DF, Grond S, etc. Validation of World Health Organization Guidelines for cancer pain relief: a 10-year prospective study. Pain. 1995 Oct;63(1):65-76
6. Laine L. The gastrointestinal effects of nonselective NSAIDs and COX-2-selective inhibitors. Semin Arthritis Rheum. 2002 Dec; 32(3 Suppl 1): 25-32
7. Sickes DH, Agrawal NM, etc. Incidence of gastroduodenal ulcers associated with valdecoxib compared with that of ibuprofen and diclofenac in patients with osteoarthritis. Eur J Gastroentero Hepatol, 2002 Oct; 14(10):1101-11
8. Sindrup SH, Arendt-Nielsen L, etc. The effect of quinidine of the analgesic effect of codeine. Eur J Clin Pharmacol. 1992;42(6)587-91
9. Otton SV, Schadel M, etc. CYP2D6 phenotype determines the metabolic conversion of Hydrocodone to Hydromorphone. Clin Pharmacol Ther. 1993 Nov; 54(5):463-72
10. Dayer P, Desmeules J, etc. Pharmacology of tramadol. Drugs. 1997; 53 Suppl 2:18-24
11. Sailvasti M, Tarkkila P, etc. Efficacy and side effects of tramadol versus oxycodone for patient controlled analgesia after maxillofacial surgery. Eur J Anaesthesiol. 1999 Dec; 16(12): 834-9

- 12 Wilder-Smith CH, Hill L, etc. Treatment of severe pain . . . a randomized study comparing analgesia, antinociception and GI effects. *Pain*. 2001 Mar; 91(1-2): 23-31
13. Gardner JS, Blough D. etc. Tramadol and seizures: a surveillance study in managed care population. *Pharmacotherapy*. 2000 Dec; 20(12): 1423-31
14. Ripple MG, Pestaner JP, etc. Lethal combination of tramadol and multiple drugs affecting serotonin. *Am. J Forensic Med Pathol*. 2000 Dec; 21(4): 370-4
15. UCSF (2000) Equin Dose Pain Card.
16. Marinella MA. Meperidine-induced generalized seizures with normal renal function. *South Med J*. 1997 May; 90(5): 556-8
17. Corey PJ, Heck AM, etc. *Ann Pharmacother*. 1999 Dec; 33(12): 1362-6
18. California Workers' Compensation Institute. FAQ Section – FAQ's researchers Etc.
19. MayoClinic.com: <http://www.mayoclinic.com/backpain>
20. Max MB, Zeigler D, etc. Effects of a single oral dose of desipramine on postoperative morphine analgesia. *J. Pain Symptom Manage*. 1992 nov; 7(8): 454-62
21. Backonja M. Glanzman RL. Gabapentin dosing for neuropathic pain: evidence from randomized, placebo-controlled clinical trials. *Clin Ther*. 2003 Jan;25(1): 81-104

PROPOSED CONTRACTING STANDARDS

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Assembly Bill 749:

Section 60, Section 4600.2 is added to the Labor code to read:

4600.2

- a. **Notwithstanding section 4600, when a self-insured employer, group of self-insured employers, insurer of an employer, or group of insurers contracts with a pharmacy, group of pharmacies, or pharmacy benefit network to provide medicines and medical supplies required by this article to be provided to injured employees, those injured employees that are subject to the contract shall be provided medicines and medical supplies in the manner prescribed in the contract for as long as medicines or medical supplies are reasonably required to cure or relieve the injured employee from the effects of the injury.**
- b. Nothing in this section shall affect the ability of employee-selected physicians to continue to prescribe and have the employer provide medicines and medical supplies that the physicians deem reasonably required to cure or relieve the injured employee from the effects of the injury.
- c. **Each contract described in subdivision (a) shall comply with standards adopted by the administrative director. In adopting those standards, the administrative director shall seek to reduce pharmaceutical costs and may consult any relevant studies or practices in other states. The standards shall provide for access to a pharmacy within a reasonable geographic distance from an injured employee's residence.**

Assembly bill 749 now allows contracts between self-insured employers, groups of self-insured employers, insurers of an employer, or groups of insurers and a pharmacy, a group of pharmacies or a pharmacy benefit network in providing medicines and medical supplies required to be provided to injured workers. The bill also specifies that these contracts must comply with contract standards that will be adopted by the administrative director. These standards shall try to reduce pharmaceutical costs, and ensure access to pharmacies by the injured employee. This part of the bill is important because these contracts can have a large impact on reductions in pharmaceutical costs, perhaps as much or more than the adoption of the Medi-Cal pharmacy fee schedule because the focus is on providing incentives to control over-utilization or costly prescribing practices.

Contracts are between self-insured or group of self insured, insurers of employer or group of employers and:

1. Pharmacy
2. Group of Pharmacies
3. PBM network

Standards are held by the workers' compensation administrative director for provisions that provide incentives to control drug use or costs and ensure access. The following standards should be considered for inclusion in any contracts:

Administrative Functions: Benefit structure and design, Maintaining network of retail pharmacy providers, Performing claims processing functions, record keeping services, and program reporting services

A. Medi-Cal System related Programs:

1. Contracted entity will ensure that the typical drugs prescribed in the workers' compensation system are reviewed for inclusion in MAC or FUL pricing limits at least annually. (expand MAC, maximum allowable cost price lists for many generic meds ie make it more comprehensive)
2. Contracted entity will show an ability to implement consistent preferred drug list and benefit design strategies
3. Contracted entity will ensure that the typical drugs prescribed in the workers' compensation system are well represented in the Medi-Cal preferred drug list by reviewing and updating the Medi-Cal systems list at least quarterly such as:
 - a. Providing a P&T committee to review or
 - b. Attending Medi-Cal P& T committees or reviewing their meeting outcomes
 - c. (acts to increase market share of specific drug products in order to win rebates from manufacturers)
4. Identify an agency or individual etc to provide program oversight and leadership in working with PBM

B. Pharmacy Network Programs:

1. Providing network or retail and mail order pharmacy services to lower ingredient and dispensing fees (establishing reimbursement rates for pharmacy network providers)
2. Entity agrees to provide a state-wide network of retail participating pharmacies which includes independent pharmacies as well as small and large pharmacy groups (chains)

C. Ability to meet industry standards in:

- i. Claims processing efficiently:
- ii. Eligibility determination & identification
- iii. Drug utilization review procedures

D. Drug Delivery systems: Have or have access to a mail service program and a program to encourage its use

E. Performance Achievement:

1. Provide documentation at least annually on progress towards meeting any full or partial drug risk (capitation) or performance guarantees in specific service areas such as
 - a. Achieving targeted levels of formulary compliance and
 - b. Generic drug utilization
 - c. Achieving performance guarantees on customer service parameters such as waiting times for customer calls to retail or mail service pharmacies, rate of pharmacy turnover in the provider network, consumers access to members of the pharmacy network, mail service turnaround time, accuracy of prescription, PBM timeliness in providing reports to clients
 - d. Documentation of Achieving promised level of savings at least quarterly
 - e. Make PBMs accountable for the quality of their value added programs

Drug Use and Cost Control Functions: Policies and programs to affect drug use targeted to pharmacists, physicians, and patients including drug payment and management, formularies, interchange programs, DUR activities, Disease management

A. Preferred Drug List Management:

2. PBM has certain programs designed to promote prescribing drugs in the “preferred drug list”
 - a. Such as prior-authorization or
 - b. TARS (as the Medi-Cal system provides)
3. Customize the preferred drug list to meet needs of the workers’ compensation population
4. PBM has certain programs designed to perform drug utilization reviews and other audits to foster compliance with the preferred drug list.
5. PBM will have a process in place for prior authorization
6. Exclude allowance of any patient co-payments in the WC program as it is not allowed

B. Generic Use Programs: PBM has certain process for generic utilization in lieu of brand-name utilization

C. Disease state management Programs: including physicians and pharmacists

1. PBM will have some utilization and management control programs targeted toward physicians such as
 - a. Therapeutic interchange programs
 - b. Disease management programs
 - c. Hire pharmacists to manage drugs
2. Provide academic detailing (letters to prescribers, education interventions, newsletters)

3. Provide incentives for priority services and negative incentives when not complying (to physicians as well as to pharmacies)

D. Drug Utilization Review Programs:

1. Include both retrospective and prospective drug utilization review to interpret patterns of drug use in relation to predetermined criteria and prevent or minimize inappropriate prescribing
2. Have programs in place to ensure drug safety from adverse drug reactions and drug interaction effects
3. Include a return to work assessment as at least one outcome measure of drug utilization review
4. DUR programs should also focus on decreasing initiation of disability and early return to work
5. PBM should monitor number and type of legal cases that arise from limitations on drugs on their drug policies
6. Provide quality assurance
7. Provide online adjudication and point of service payment programs
8. Manage success of first fill programs
9. Provide provider profiling and outcomes assessment
10. Provide therapy guidelines management for diseases common in workers' compensation such as pain management
11. Provide stop therapy protocol management (monitoring return to work)
12. PBM will have a mechanism in place to monitor over-utilization, such as:
 - a. Early refills
 - b. Duplicate prescriptions
 - c. Drugs not commonly associated with workers' compensation
 - d. Over-use of branded drugs
13. Quality Control Programs

E. Manufacturer Rebate Programs

F. Contracting:

1. Value based contracting: Medicaid agrees to contract only with providers who agree to a certain contract with stringent provider qualifications and access requirements

G. Performance standards and monitoring:

1. Performance standards: monitors performance on quality and patient satisfaction measures (report cards, surveys, published reports)

Financial arrangements between contracted entity and clients:

1. Experience

- a. Proof that they can perform in a Medicaid environment: ie access to pricing software or Medi-Cal pricing information which can be updated monthly

- b. Proof that they can perform in a workers' compensation environment: ie provide anticipated Medi-Cal pricing structure for drugs typically used by WC claimants
- c. Adequate record-keeping ability

2. Financial integrity

3. Maintain confidential patient information and follow all HIPPA regulations and rules

4. Conflicts of Interest disclosure

- a. disclose ownership or financial ties to a drug manufacturer that could pose a conflict of interest
- b. Disclosure of any potential or real conflicts of interest in promotion of specific products by PBMs
- c.

5. Financial Data Disclosure

- a. PBM will update monthly and disclose quarterly to the administrative director the "lowest paid Medi-Cal amounts by NDC number for each drug.
- b. PBM will disclose their administrative fee structure for basic services and additional fees for any "value-added" components
 - c. Provide full explanation of the PBM charge mechanism which is no more than the usual and customary charge to other clients such as:
 - i. Transaction fee charged per prescription claim or
 - ii. Flat rate charge/month for extra services or
 - iii. Annual flat rate charge for extra services
- d. Specify who is receiving any rebate money obtained for WC claimants and the amount received. This rebate money should either be shared or be returned to the client
- e. PBM should make any drug utilization data available to the program administrator for independent analysis

Definitions:

Pharmacy Benefit Managers (PBMs) are companies that administer drug benefit programs for employers and health insurance carriers. Many PBMs originated as claims processors and some continue primarily with this function. However, most PBMs provide a wide range of services including formulary management, disease management, and pharmacy network development

Preferred Drug Lists or formulary is a list of preferred drugs which are listed to encourage their use as opposed to drugs not on the list. Preferred drug lists are label specific with drugs in every class included on the list but not every manufacturer of that drug is on the list. The Medi-Cal system has a preferred drug list, but will cover all drugs if they are medical necessary. A treatment authorization request is required however for

drugs that are not on the preferred list. The level of manufacturer rebates is often contingent on the ability to favor drugs listed on the formulary, providing volume guarantees.

Disease Management is the application of a defined process to guide the delivery of pharmaceutical care for a specific disease and includes the education of the physician, pharmacist and the patient. Disease management focuses on prevention rather managing acute episodes, and encourages compliance with a defined process of care.

Drug Utilization Reviews (DUR) are programs designed to ensure that the quality and efficient pharmaceutical care are provided. DUR programs include therapeutic appropriateness of a drug therapy, monitoring for potential drug-drug interactions, checking for drug alerts, and potential adverse drug reactions, and monitoring for over or under utilization of drugs. Much of DUR is provided using on-line systems.

Pharmacy Networks are often developed and managed and typically include most pharmacists in a given area with participating pharmacies usually offering lower discounts to be a part of the network. Forming networks involves recruiting and credentialing pharmacies, negotiating discounts on drug prices, monitoring pharmacies for quality and customer service, auditing pharmacies, and providing technical support.

Access Standards: Pharmacy networks are often formed to meet patient access standards to ensure convenient access for their members. This access is usual to provide access to the members within a 5 mile radius, or within 3 miles for urban areas, 5 miles for suburban areas, and 10 miles for rural areas.

Mail Order Pharmacies use the technology of automated systems to count and dispense medications while checking for drug interactions and other problems to promote safety and within at least 3-5 days. By automating the dispensing process, mail order pharmacies require lower dispensing fees, giving mail order a 5-10% discount over retail pharmacies. They also generally promote generic substitution efficiently.

Factors to Consider when evaluating a PBM contract:

1. PBMs can administer differing plan designs and generic substitution programs across retail and mail order and across all lines of business
2. PBM performs audits of contracted pharmacy providers and audits of its own financial status to the administrator or insurer
3. All pharmacy claims are adjudicated electronically, and eligibility files are updated regularly
4. Has online drug utilization review edits and reporting tools to identify quality issues and cost-control opportunities. Has advanced information technology tools available to provide customized utilization analysis
5. Makes apparent all forms of financial assistance from vendors including rebates and contracted discounts, unrestricted grants etc and where they come from and what they are used for.

6. Has a system for communicating prescription benefit, formulary, utilization management, and disease management initiatives to physicians and patients.
7. Specifies in writing the prescription drug reimbursement rates for network pharmacies and mail service and uses the Medi-Cal reimbursement system through their software or through monthly acquisition of their rates (by ndc # monthly)
8. Specifies how the PBM will share with the insurer any savings from pharmaceutical contracts and cost-improvement programs
9. Specifies the administrative fees associated with prescription claims, network management, utilization management, and providing management reports, and how they will be charged either per adjudicated claim (most common method), per member per month, or by an annual fee-for-service charge
10. Specify performance guarantees that are available to ensure that administrative, quality and customer service standards are met and include penalties for not meeting these.
11. Performance: Has the PBM fulfilled its contractual and fiduciary responsibilities?
12. Management systems: Include quarterly reports analyses and concise executive summaries, online data retrieval capabilities, electronic prescribing, enough support personnel
13. Clinical programs: online DUR programs, and quality improvement programs, POS, disease management
14. Customer satisfaction: Regularly monitor patient and provider satisfaction, Specify and check for meeting of service quality standards.